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TO THE BOARD OF PATENT APPEALS AND INTERFERENCES

Appl. No.	:	10/675,611	Confirmation No. 6361
Appellant	:	William J. Boyle et al.	
Filed	:	September 29, 2003	
Title	:	EMBOLIC FILTERING DEVICES	
Art Unit	:	3738	
Examiner	:	Christopher D. Prone	
Docket No.:	:	ACSES-63641 (G3386USP1)	
Customer No.	:	24201	January 19, 2010

Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

APPEAL BRIEF

Dear Sir:

This Appeal Brief is being filed pursuant to the Notice of Appeal filed on July 16, 2009 from the Final Office Action dated April 21, 2009. A One-Month Request for an Extension of Time to respond is being filed concurrently herewith.

INTRODUCTION

The present invention is directed to filtering devices and systems used, for example, when an interventional procedure is being performed in a stenosed or occluded region of a body vessel to capture embolic material that may be created and released into the body fluid during the procedure. The present invention is more particularly directed to an embolic filtering system using special guide wire

torque devices that facilitate the rapid removal of a peel-away delivery sheath used to position the filtering device within the patient's vasculature.

The present application, U.S. Serial No. 10/675,611 was filed on September 29, 2003 and is a continuation-in-part of U.S. Serial No. 10/377,285 filed on February 27, 2003.

I. REAL PARTY IN INTEREST

The real party in interest in this appeal is ABBOTT CARDIOVASCULAR SYSTEMS INC., 3200 Lakeside Drive, Santa Clara, CA 95054, which is a division of Abbott Laboratories, 100 Abbott Park Road, Abbott Park, Illinois 60664-3500. This application was originally assigned by the inventors, WILLIAM J. BOYLE, JOHN E. PAPP, CHARLES R. PETERSON, PAUL F. MULLER, DONALD SCHWARTEN and KATHERINE J. LIND to ADVANCED CARDIOVASCULAR SYSTEMS INC., by Assignment executed on October 30, 2003, November 4, 2003 and August 11, 2004, which was recorded by the U.S. Patent Office on August 16, 2004 beginning at Reel 015681, Frame 0859; Reel 015682, Frame 0294 and Reel 015713, Frame 0241. ABBOTT CARDIOVASCULAR SYSTEMS INC is the owner of ADVANCED CARDIOVASCULAR SYSTEMS INC.

II. RELATED APPEALS AND INTERFERENCES

With respect to other appeals or interferences that will directly effect, or be directly effected by, or have a bearing on the Board's decision on this appeal, it is to be noted that is believed there are no such appeals or interferences known to the Appellant.

III. STATUS OF CLAIMS

A. Total Number of Claims in the Application

The claims in the application are: Claims 1, 2, 4, 7-10 and 12-27. Claims 3, 5 and 6 have been canceled without prejudice. Claim 11 has been withdrawn in view of an election of species requirement.

B. Status of All Claims on Appeal

Claims 1, 2, 4, 7-10 and 12-27 were rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,152,946 to Broome et al. (the "Broome patent") in view of U.S. Patent No. 5,161,534 to Berthiaume (the Berthiaume patent") and in further view of U.S. Patent No. 3,459,184 to Ring (the "Ring patent"). Claims 3, 5 and 6 have been canceled without prejudice. Claim 11 has been withdrawn in view of an election of species requirement.

C. Claims on Appeals

The claims on appeal are each of pending claims 1, 2, 4, 7-10 and 12-27. A copy of the claims being appealed is appended as Exhibit 1.

IV. STATUS OF AMENDMENTS

On April 21, 2009, the Examiner issued a final Office Action maintaining the §103 rejections of the pending claims. Appellant filed a Pre-Appeal Brief Request For Review on July 16, 2009. An Notice of Panel Decision issued on November 10, 2009 stating that there is still at least one issue for appeal. The finally rejected claims attached to this brief are the subject of this appeal.

V. SUMMARY OF THE CLAIMED SUBJECT MATTER

Claims 1, 2, 4, 7 and 15-27 are directed to an embolic filtering system used to capture embolic debris in a body vessel which includes a torque device for rotating a guide wire and effecting the splitting of a sheath which is co-axially disposed over the guide wire and a filtering device disposed on the guide wire. Claims 8-10 and 12-14 are directed solely to a torque device for rotating a guide wire and effecting the splitting of a sheath which is co-axially disposed over the guide wire.

Independent Claim 1

Independent claim 1 is supported in the drawings and specification as follows:

1. An embolic filtering system (page 14, paragraph [024], FIG. 1A, # 20) used to capture embolic debris in a body vessel, comprising:

an expandable filter assembly (page 14, paragraph [024], FIG. 1A, # 22) including a self-expanding frame (page 14, paragraph [024], FIG. 1A, # 24) moveable between an expanded position and an unexpanded position, the expandable filter being disposed on a guide wire (page 14, paragraph [024], FIG. 1A, # 28);

a filtering element (page 14, paragraph [024], FIG. 1A, # 26) attached to and movable with the frame;

a sheath (page 14, paragraph [024] and page 15, paragraph [026], FIGS. 1C, 2A and 2B, # 30) having a lumen for receiving the guide wire and having a distal end portion and a proximal end, the distal end portion of the sheath being adapted to receive the expandable filter assembly for maintaining the filter assembly in the unexpanded position (page 15, paragraph [026], FIG. 2A) and

being movable to expose the filter assembly (page 15, paragraph [026], FIG. 2B); and

a torque device (page 32, paragraph [054], FIGS 12A-12C, # 280) including:

a handle (page 32, paragraph [054], FIGS. 12A-12C, # 262) with a lumen (page 32, paragraph [054], FIGS. 12A-12C, # 287) extending therethrough for receiving the guide wire which allows the handle to be directly mountable on the guide wire,

means (page 32, paragraph [054], FIGS. 12A-12C, # 264) associated with the handle for locking the guide wire to the torque handle to allow the user to rotate the guide wire,

a side port (page 32, paragraph [054], FIGS. 12A-12C, # 288) adapted to receive the proximal end of the sheath which allows a portion of the guide wire to shear (page 33, paragraph [056], FIGS. 12A-12C) the sheath from the guide wire through retraction of the sheath through the side port; and

an extension arm (page 32, paragraph [054], FIGS. 12A-12C, # 284) extending from the handle which includes a distal end (page 32, paragraph [054], FIGS. 12A-12C, # 286) having an opening (page 32, paragraph [054], FIGS. 12A-12C, # 285) adapted to receive both the guide wire and the sheath, the end of the extension arm being disposed longitudinally away from the side port.

Independent Claim 8

Independent claim 8 is supported in the drawings and specification as follows:

8. A torque device (page 32, paragraph [054], FIGS 12A-12C, # 280) for rotating a guide wire (page 14, paragraph [024], FIG. 1A, # 28) and effecting the

splitting of a sheath (page 14, paragraph [024] and page 15, paragraph [026], FIGS. 1C, 2A and 2B, # 30) which is co-axially disposed over the guide wire (page 14, paragraph [024], FIG. 1A, # 28), the torque device comprising:

a handle (page 32, paragraph [054], FIGS. 12A-12C, # 262) having a lumen (page 32, paragraph [054], FIGS. 12A-12C, # 287) extending therethrough for receiving the guide wire;

means (page 32, paragraph [054], FIGS. 12A-12C, # 264) associated with the handle to lock the guide wire within the lumen of the handle; and

a side port (page 32, paragraph [054], FIGS. 12A-12C, # 288) adapted to receive the proximal end of the sheath which allows a portion of the guide wire to shear (page 33, paragraph [056], FIGS. 12A-12C) the sheath from the guide wire through proximal retraction of the sheath through the side port.

Independent Claim 15

Independent claim 15 is supported in the drawings and specification as follows:

15. An embolic filtering system (page 14, paragraph [024], FIG. 1A, # 20) used to capture embolic debris in a body vessel, comprising:

a guide wire (page 14, paragraph [024], FIG. 1A, # 28);

a filter device (page 14, paragraph [024], FIG. 1A, # 22, 24 and 26) disposed on the guide wire;

a sheath (page 14, paragraph [024] and page 15, paragraph [026], FIGS. 1C, 2A and 2B, # 30) having a distal end portion and a proximal end, the distal end portion of the sheath being adapted to receive and maintain the filter device in an unexpanded position (page 15, paragraph [026], FIG. 2A) and

removable from the filter device (page 15, paragraph [026], FIG. 2B), the sheath having a guide wire lumen for receiving the guide wire; and

a torque device (page 32, paragraph [054], FIGS 12A-12C, # 280) having a handle portion page 32, paragraph [054], FIGS. 12A-12C, # 262) directly mountable on the guide wire to allow the user to rotate the guide wire, the handle having a lumen (page 32, paragraph [054], FIGS. 12A-12C, # 287) extending therethrough for receiving the guide wire, the torque device having a side port (page 32, paragraph [054], FIGS. 12A-12C, # 288) adapted to receive the proximal end of the sheath which allows a portion of the guide wire to shear (page 33, paragraph [056], FIGS. 12A-12C) the sheath from the guide wire by the retraction of the sheath through the side port.

Independent Claim 27

Independent claim 27 is supported in the drawings and specification as follows:

27. An embolic filtering system (page 14, paragraph [024], FIG. 1A, # 20) used to capture embolic debris in a body vessel, comprising:

a guide wire (page 14, paragraph [024], FIG. 1A, # 28);

a filter device (page 14, paragraph [024], FIG. 1A, # 22, 24 and 26) disposed on the guide wire;

a sheath (page 14, paragraph [024] and page 15, paragraph [026], FIGS. 1C, 2A and 2B, # 30) having a distal end portion and a proximal end, the distal end portion of the sheath being adapted to receive and maintain the filter device in an unexpanded position (page 15, paragraph [026], FIG. 2A) and removable from the filter device (page 15, paragraph [026], FIG. 2B), the sheath having a guide wire lumen for receiving the guide wire; and

a torque device (page 32, paragraph [054], FIGS 12A-12C, # 280) having a handle portion page 32, paragraph [054], FIGS. 12A-12C, # 262) directly mountable on the guide, the handle having a lumen (page 32, paragraph [054], FIGS. 12A-12C, # 287) extending therethrough for receiving the guide wire and a locking mechanism (page 32, paragraph [054], FIGS. 12A-12C, # 264) for locking the torque device to the guide wire, a second lumen (page 32, paragraph [054], FIGS. 12A-12C, # 288) formed on the handle separate and offset from the guide wire receiving lumen which allows a portion of the guide wire to shear (page 33, paragraph [056], FIGS. 12A-12C) the sheath away from the guide wire by the retraction of the sheath through the second lumen.

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

The grounds for appeal are as follows:

GROUND I

Whether claims 1, 2, 4, 7-10 and 12-27 are obvious under 35 U.S.C. § 103(a) over the Broome patent (Exhibit 2) in view of the Berthiaume patent (Exhibit 3) and in further view of the Ring patent (Exhibit 4).

VII. ARGUMENT

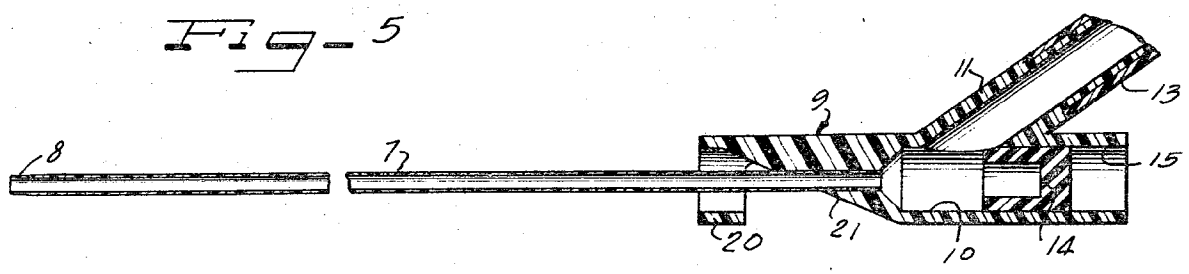
GROUND I

A. Whether Claims 1, 2, 4, 7-10 and 12-27 are Obvious over the Broome, Berthiaume and Ring Patents

All of the pending claims 1, 2, 4, 7-10 and 12-27 were rejected under 35 U.S.C. § 103(a) as being unpatentable over the Broome patent in view of the Berthiaume patent and in further view of the Ring patent. First, it is noted that the Ring patent is directed to an intravenous catheter placement unit which utilizes a **solid needle 1 to implant a plastic catheter 7 into a patient**. The Examiner has

taken the position that **this plastic catheter 7 constitutes a guide wire**, as the term guide wire is used in the art, since "any member that can be used to track a catheter or tube to a desired site can be considered a guidewire." (page 4 of the final Office Action) The Examiner's position is significant since all of the pending claims recite a torque device which utilizes **a portion of the guide wire to shear the sheath away from the guide wire through retraction of the sheath through a side port or second lumen located on the torque device**. Thus, it is the stiffness of the guide wire as it is held in the torque device that provides the needed component that actually cuts or shears the sheath as the sheath is being retracted. The flexible plastic catheter 7 of the Ring patent would simply fail to perform this function since it lacks the stiffness needed to shear the sheath. Moreover, the Ring patent discloses the use of a pre-formed slit 19 along the length of the sheath 18 which allows for the easy removal of the sheath 18. An inclined surface 21 formed on the proximal fitting is used to separate the pre-formed slit 19 of the sheath 18 allowing the sheath to be easily removed from the catheter 7. Shearing or tearing of the sheath 18 is not contemplated by the Ring patent. One skilled in the art would recognize this shortcoming in the Ring patent. The Examiner also has taken the position that the Ring device discloses a side port adapted to receive the proximal end of the sheath. Appellant strongly disagrees with each of the Examiner's positions.

Initially, it is noted that the Ring device lacks a side port for receiving the sheath. The Examiner identifies an alleged sideport near reference numeral 21 in the drawing of the Ring patent. However, this structure is not a separate sideport, but rather, is merely the space formed between the loop 20 and the main body of the tubular fitting 9. Figure 5 of the Ring patent, reproduced below, shows the space which extends proximally from the loop 20 to the main body of the fitting 9.



There simply is no separate side port that receives the sheath. Appellant acknowledges that the inclined surface 21 does cause the sheath 18 to bend away from the catheter 7 and needle 1 during usage; however, a separate side port is not present. For this reason alone, the Ring patent fails to disclose the structure recited in the pending claims.

In the context of the present invention, the term "guide wire" is properly construed to mean a flexible elongate wire that can used in combination with a number of medical devices, such as balloon catheters, atherectomy devices, filtering devices, just to name a few. The guide wire is generally used with the medical device to allow the device to be tracked along the wire from its free proximal end towards its distal end position within the patient's body, such that the guide wire acts as a "rail" or guide for the positioning of the device. This construction of the term "guide wire" is consistent with the meaning understood by those skilled in the art. In general, guide wires are used to find and secure a pathway through a patient's artery and the stenotic lesion. The guide wire allows the subsequent passage of therapeutic devices thereover once the guide wire has been advanced into the artery of interest.

Appellant submits that the Ring patent fails to disclose a guide wire as the term is known to one skilled in the art. The Examiner has identified the plastic catheter 7 disclosed in the ring patent as a "guide wire." Appellant submits that this catheter 7 is not a guide wire and does not function as a guide wire as this term is known in the medical field. The Examiner maintains that it indeed functions as a

guide wire. However, it is simply a plastic tubing insertable into the patient for administering fluids. The construction of the proximal portion of the unit shown in the Ring patent, as shown above in Figure 5, actually prevents the catheter 7 from being used as guide wire. As can be seen in Figure 5, the proximal end of the catheter 7 is fixedly attached to the tubular fitting 9. Therefore, it would be impossible to use this catheter 7 as a "guide wire," as suggested by the Examiner, due to the presence of this fixing 9. This fitting at the proximal end of the catheter 7 would simply prevent one from using the catheter 7 as a guide wire. Additionally, this soft plastic catheter 7 would be incapable, by itself, of causing the sheath 18 to shear. Rather, it is the **inclined surface 21 of** the Ring device which causes the pre-formed split 19 formed on the sheath 18 to open allowing the sheath 18 to be removed from the tubular catheter 7.

There also appears to be no motivation for one skilled in the art in placing the Ring sheath splitter 21 on the Berthiaume torque device as suggested by the Examiner. Appellant only agrees with the Examiner's position that the Berthiaume torque device could be used on the embolic filter device disclosed in the Broome patent. Additionally, the sheath 18 disclosed in the Ring patent is not utilized to restrain an embolic filtering device as recited in pending claims. In fact, this sheath 18 is not intended for insertion into the patient's vasculature since the sheath 18 merely acts as a sterile barrier for the tubular catheter 7 which is the actual component being inserted into the patient. The proximal end of the device is retracted proximally to insure that the sheath 18 never enters the vasculature of the patient. In this manner, the plastic catheter 7 remains sterile as it is being placed into the patient.

In view of these apparent differences between the Ring device and the devices disclosed in the Broome and Berthiaume patents, Appellant believes that

the Examiner has merely used the present claims as a road map and has selectively chosen unrelated components in prior art references in an attempt to recreate the structure defined in the pending claims. Additionally, the combinations of prior art suggested by the Examiner fail to justify why one skilled in the art would be motivated to combine them in the first place. For these reasons alone, the obviousness rejections of the pending claims should be withdrawn.

Even assuming *arguendo* that one skilled in the art would combine the Ring patent with the Berthiaume patent**,** which is highly contested by Appellant, one skilled in the art would recognize that it is the inclined surface 21 of the Ring device that functions to open the pre-formed slit 19 formed on the sheath 18. The Ring patent states the following at Column 3, lines 50-70:

> The catheter and needle are maintained in a sterile condition by a sheath **18** having a slit, indicated at **19** in FIGURE 4, extending lengthwise of the sheath along the top side thereof. The sheath is made from a suitable plastic material, such as polyethylene, and no sealing means are required at the slit, since the resiliency of the sheath tends to maintain the slit closed……. The sheath extends through a loop **20** which may be integrally formed on the end of the catheter **9**, and behind that loop the fitting is provided with a downwardly inclined surface **21** to cause the sheath to bend away from the catheter and needle during manipulation of the placement unit, as seen in FIGURES 2 and 3, the slit **19** of the sheath opening sufficiently to permit the sheath to be readily drawn off the catheter and needle.

Again, it is noted that the Ring device does not shear or tear the sheath in any manner as is recited in the claims. Therefore, one skilled in the art in reading the teachings of the Ring patent would utilize a sheath having a pre-formed slit along its length and a component in the form of an inclined surface on any type of torque device that could possibly result from the suggested combination of the Ring and Berthiaume patents. In such a combination, it would be the inclined surface, not the guide wire itself, that would perform the shearing function. Therefore, the

suggested combination of the Ring patent with the Berthiaume patent would not create the structure recited in all of the claims.

B. Missing Components Recited in the Dependent Claims

In the final Office Action, the Examiner fails to identify numerous components recited in some of the dependent claims. These dependent claims are discussed below.

Claims 4 and 12

Both claims 4 and 12 further require the torque device to include a tubular member extending distally from the distal end of the extension arm which includes a lumen aligned with and in communication with the opening of the distal end that is adapted to receive the guide wire and sheath. No such structure was identified by the Examiner in the final Office Action. Therefore, the Examiner has failed to prove a *prima facia* case against these claims.

Claim 17

Claim 17 requires that at least a portion of the wall of the sheath has reduced thickness to enhance the ability of the sheath to shear as the sheath is retracted through the side port. No such structure was identified by the Examiner in the final Office Action. The split found along the length of the sheath 18 is not a reduced thickness in the wall. Therefore, the Examiner has failed to prove a *prima facia* case against this claim.

Claim 19

Claim 19 further requires the side port of the torque device to have a funnel shaped opening. No such structure was identified by the Examiner in the final Office Action. Therefore, the Examiner has failed to prove a *prima facia* case against this claim.

Claim 20

Claim 20 further requires the torque device to include a component to prevent the guide wire from kinking as the sheath is retracted through the side port. No such structure was identified by the Examiner in the final Office Action. Therefore, the Examiner has failed to prove a *prima facia* case against this claim.

Claim 22

Claim 22 further requires the extension arm to be integrally formed with the means for locking the handle to the guide wire. No such structure was identified by the Examiner in the final Office Action. Therefore, the Examiner has failed to prove a *prima facia* case against this claim.

Claim 23

Claim 23 further requires the extension arm to be removable attached to the handle. No such structure was identified by the Examiner in the final Office Action. Therefore, the Examiner has failed to prove a *prima facia* case against this claim.

For all of these additional reasons, the Examiner has failed to present sufficient proof of obviousness against the pending claims. The obviousness rejections of the pending claims should be withdrawn.

VIII. CLAIM APPENDIX

See Exhibit 1.

IX. EVIDENCE APPENDIX

None.

X. RELATED PROCEEDINGS APPENDIX

NONE

XI. CONCLUSION

Appellant respectfully requests that the obviousness rejections based on the combination of the Broome, Berthiaume and Ring patents be withdrawn. The combination of these references fails to create the basic structure recited in all of the pending claims. Accordingly, all of the pending claims have been incorrectly rejected by the Examiner.

The fee of $540.00 for the filing of Appellant's Appeal Brief is being paid concurrently herewith. The Commissioner is hereby authorized, however, to charge any additional fees which may be required, or credit any overpayment, to Deposit Account No. 06-2425.

Respectfully submitted,

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EXHIBIT 1

EXHIBIT 1 - Appealed Claims

1. An embolic filtering system used to capture embolic debris in a body vessel, comprising:

an expandable filter assembly including a self-expanding frame moveable between an expanded position and an unexpanded position, the expandable filter being disposed on a guide wire;

a filtering element attached to and movable with the frame;

a sheath having a lumen for receiving the guide wire and having a distal end portion and a proximal end, the distal end portion of the sheath being adapted to receive the expandable filter assembly for maintaining the filter assembly in the unexpanded position and being movable to expose the filter assembly; and

a torque device including:

a handle with a lumen extending therethrough for receiving the guide wire which allows the handle to be directly mountable on the guide wire,

means associated with the handle for locking the guide wire to the torque handle to allow the user to rotate the guide wire,

a side port adapted to receive the proximal end of the sheath which allows a portion of the guide wire to shear the sheath from the guide wire through retraction of the sheath through the side port; and

an extension arm extending from the handle which includes a distal end having an opening adapted to receive both the guide wire and the sheath, the end of the extension arm being disposed longitudinally away from the side port.

2. The embolic filtering system of claim 1, wherein the sheath includes a split seam extending therethrough from the proximal end to a location proximal to the distal end portion to enhance the ability of the sheath to shear as the sheath is retracted through the side port.

3. (Canceled)

4. The embolic filtering system of claim 1, further including a tubular member extending distally from the distal end of the extension arm which includes a lumen aligned with and in communication with the opening of the distal end that is adapted to receive the guide wire and sheath.

5. (Canceled)

6. (Canceled)

7. The embolic filtering system of claim 1, wherein the side port is located at an offset location from the axis defined by the guide wire.

8. A torque device for rotating a guide wire and effecting the splitting of a sheath which is co-axially disposed over the guide wire, the torque device comprising:

a handle having a lumen extending therethrough for receiving the guide wire;

means associated with the handle to lock the guide wire within the lumen of the handle; and

a side port adapted to receive the proximal end of the sheath which allows a portion of the guide wire to shear the sheath from the guide wire through proximal retraction of the sheath through the side port.

9. The torque device of claim 8, wherein the sheath includes a split seam extending therethrough from the proximal end to a location proximal to the distal end portion to cause the sheath to shear as the sheath is pulled through the side port.

10. The torque device of claim 8, wherein the torque device includes an extension arm extending from the handle which includes a distal end having an opening adapted to receive both the guide wire and the sheath, the distal end of the extension arm being disposed longitudinally away from the side port.

11. (Withdrawn)

12. The torque device of claim 10, further including a tubular member extending distally from the distal end of the extension arm which includes a lumen aligned with and in communication with the opening of the distal end that is adapted to receive the guide wire and sheath.

13. The torque device of claim 10, wherein the opening of the distal end of the extension arm is aligned with the lumen of the handle.

14. The torque device of claim 10, wherein the side port is aligned offset from the opening of the distal end of the extension arm.

15. An embolic filtering system used to capture embolic debris in a body vessel, comprising:

a guide wire;

a filter device disposed on the guide wire;

a sheath having a distal end portion and a proximal end, the distal end portion of the sheath being adapted to receive and maintain the filter device in an unexpanded position and removable from the filter device, the sheath having a guide wire lumen for receiving the guide wire; and

a torque device having a handle portion directly mountable on the guide wire to allow the user to rotate the guide wire, the handle having a lumen extending therethrough for receiving the guide wire, the torque device having a side port adapted to receive the proximal end of the sheath which allows a portion of the guide wire to shear the sheath from the guide wire by the retraction of the sheath through the side port.

16. The embolic filtering system of claim 15, wherein at least a portion of the sheath includes a split seam extending therethrough to enhance the ability of the sheath to shear as the sheath is retracted through the side port.

17. The embolic filtering system of claim 15, wherein at least a portion of the wall of the sheath has reduced thickness to enhance the ability of the sheath to shear as the sheath is retracted through the side port.

18. The embolic filtering system of claim 15, wherein the torque device includes:

a locking mechanism associated with the handle for locking the guide wire within the lumen of the handle; and

the side port is located at an offset position from the lumen which receives the guide wire.

19. The embolic filtering system of claim 15, wherein the side port has a funnel shaped opening.

20. The embolic filtering system of claim 15, wherein the torque device includes a component to prevent the guide wire from kinking as the sheath is retracted through the side port.

21. The embolic filtering system of claim 1, wherein the means for locking the handle to the guide wire is attached to the handle.

22. The embolic filtering system of claim 21, wherein the extension arm is integrally formed with the means for locking the handle to the guide wire.

23. The embolic filtering system of claim 1, wherein the extension arm is removable attached to the handle.

24. The embolic filtering system of claim 1, wherein the locking means of the torque device includes a collet associated with the handle which applies force on the guide wire to lock it to the handle.

25. The torque device of claim 8, wherein the locking means includes a collet associated with the handle which applies force on the guide wire to lock it to the handle.

26. The embolic filtering system of claim 15, wherein the locking means of the torque device includes a collet associated with the handle which applies force on the guide wire to lock it to the handle.

27. An embolic filtering system used to capture embolic debris in a body vessel, comprising:

a guide wire;

a filter device disposed on the guide wire;

a sheath having a distal end portion and a proximal end, the distal end portion of the sheath being adapted to receive and maintain the filter device in an unexpanded position and removable from the filter device, the sheath having a guide wire lumen for receiving the guide wire; and

a torque device having a handle portion directly mountable on the guide, the handle having a lumen extending therethrough for receiving the guide wire and a locking mechanism for locking the torque device to the guide wire, a second lumen formed on the handle separate and offset from the guide wire receiving lumen which allows a portion of the guide wire to shear the sheath away from the guide wire by the retraction of the sheath through the second lumen.

US006152946A

United States Patent [19]

Broome et al.

[11] **Patent Number: 6,152,946**

[45] **Date of Patent: Nov. 28, 2000**

[54] **DISTAL PROTECTION DEVICE AND METHOD**

[75] Inventors: **Thomas E. Broome**, Hopkins; **John M. K. Daniel**, Plymouth; **Thomas R. Hektner**, Medina, all of Minn.

[73] Assignee: **SciMed Life Systems, Inc.**, Maple Grove, Minn.

[21] Appl. No.: **09/035,740**

[22] Filed: **Mar. 5, 1998**

[51] **Int. Cl.**[7] **A61M 29/00**

[52] **U.S. Cl.** **606/200**

[58] **Field of Search** 606/200, 198, 606/191, 159

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764684	9/1980	U.S.S.R. .
2 020 557	1/1983	United Kingdom .
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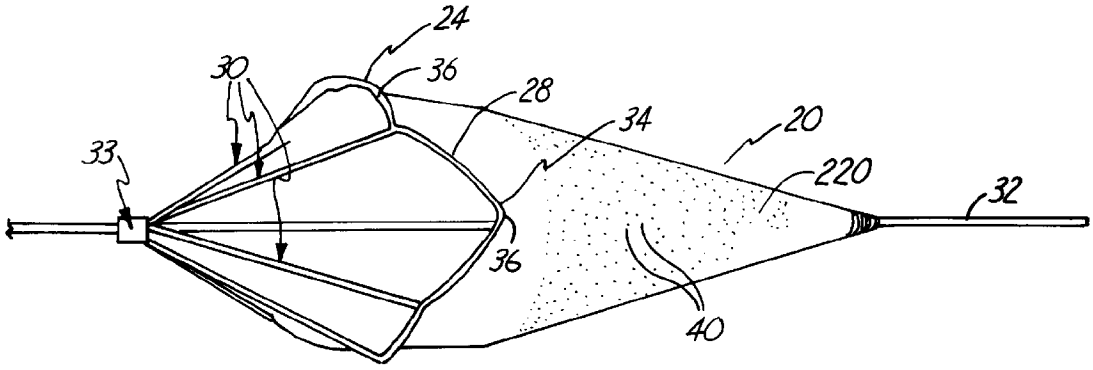
Primary Examiner—Jeffrey A. Smith

Attorney, Agent, or Firm—Crompton, Seager & Tufte LLC.

[57] **ABSTRACT**

A device adapted for deployment in a body vessel for collecting floating debris and emboli in a filter. The device includes a collapsible proximally tapered frame for operably supporting the filter between a collapsed insertion profile and an expanded deployment profile. The tapered collapsible frame includes a mouth which is sized to extend to walls of the body vessel in the expanded deployed profile to seal the filter relative to the body vessel for collecting debris floating in the body vessel.

15 Claims, 12 Drawing Sheets



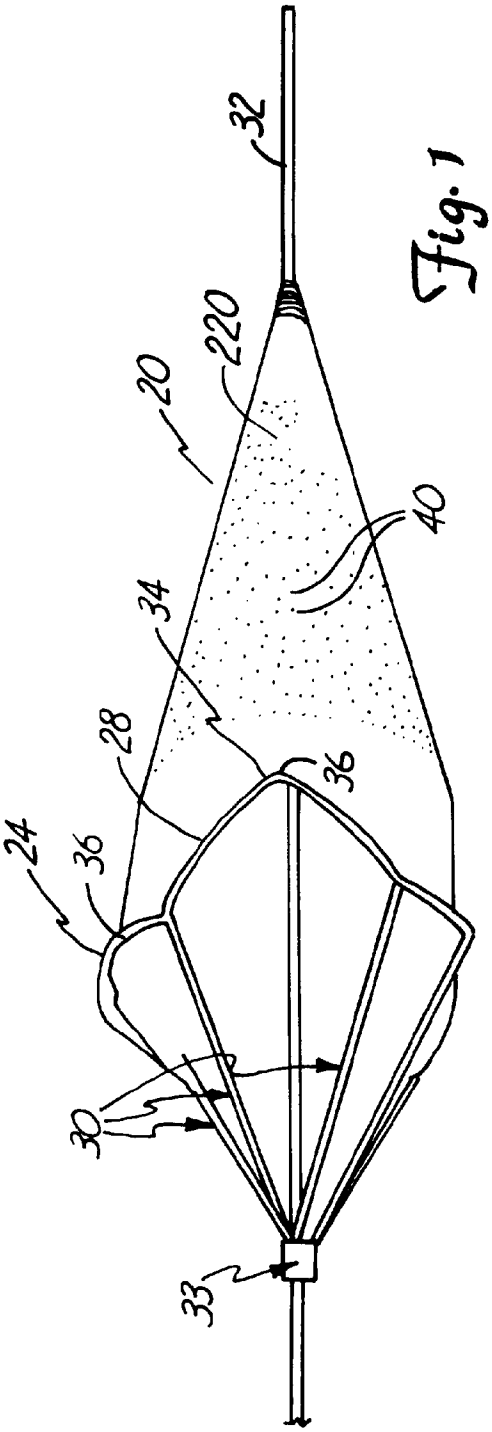


Fig. 1

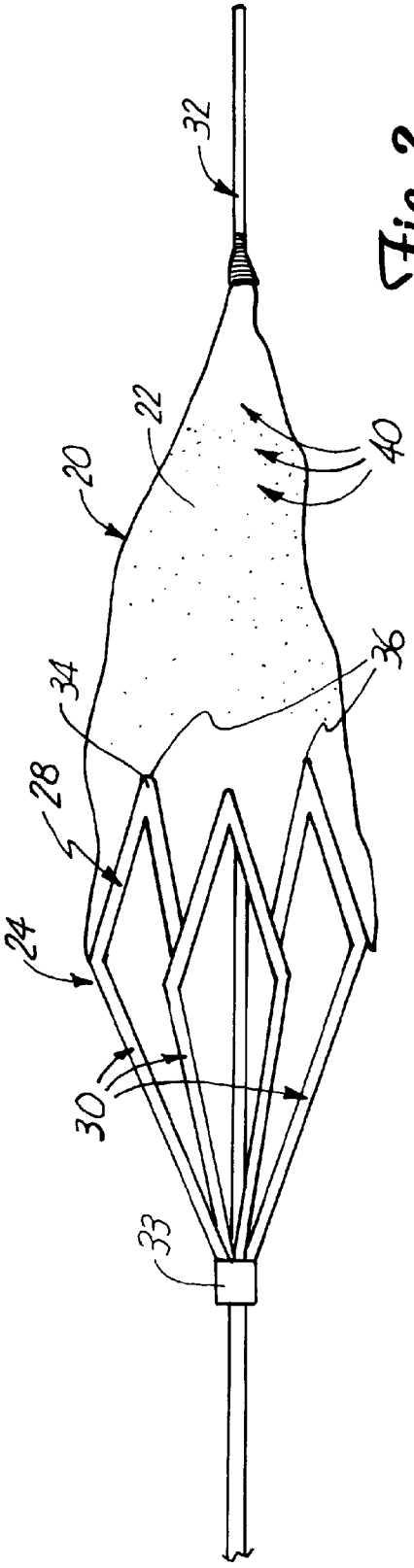


Fig. 2

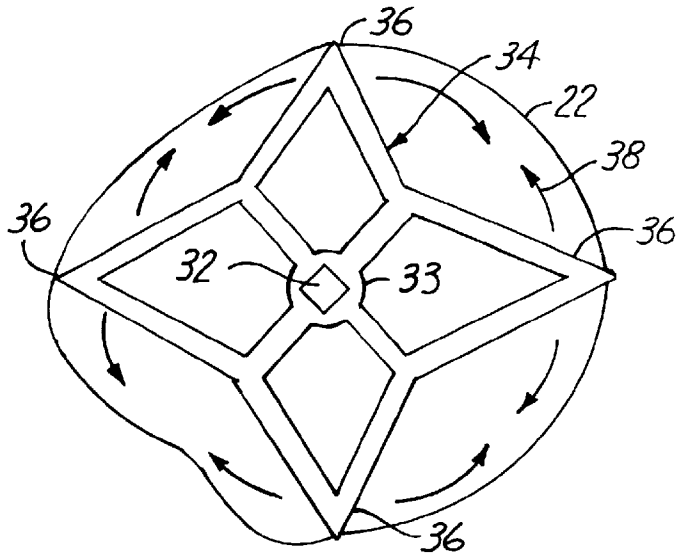


Fig. 3

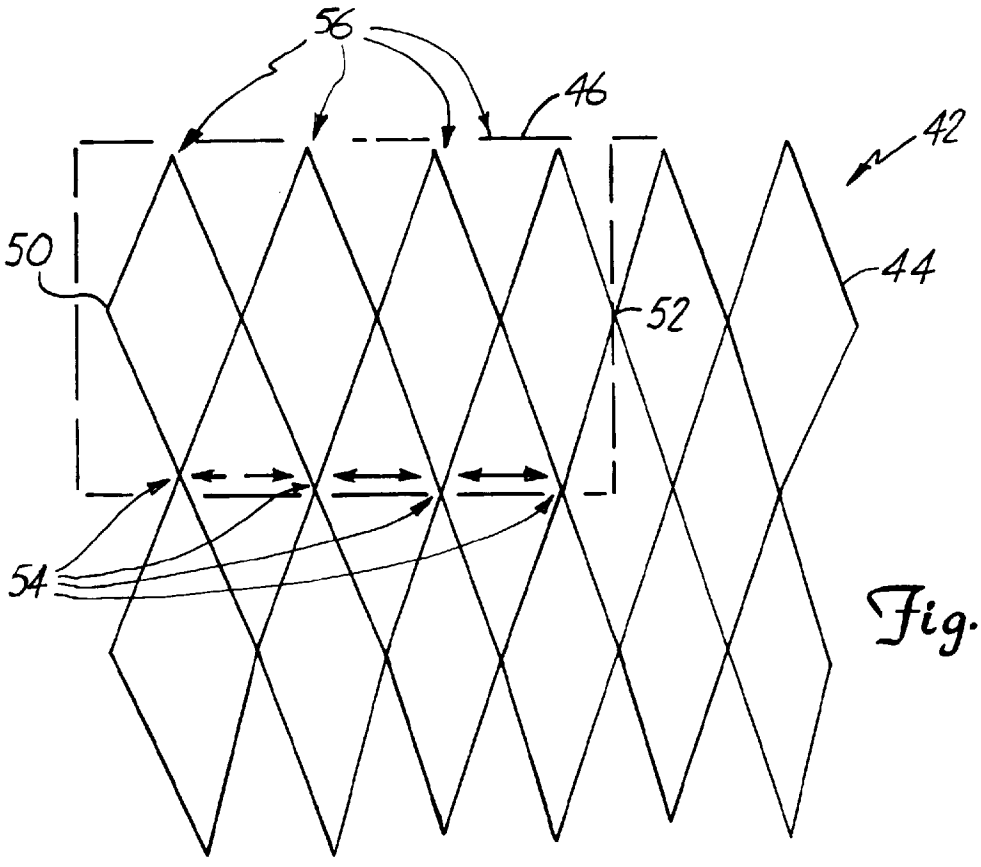


Fig. 4

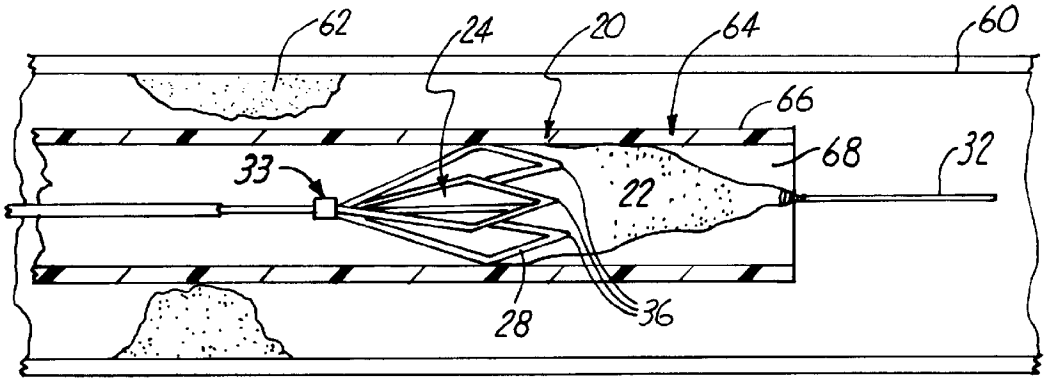


Fig. 5

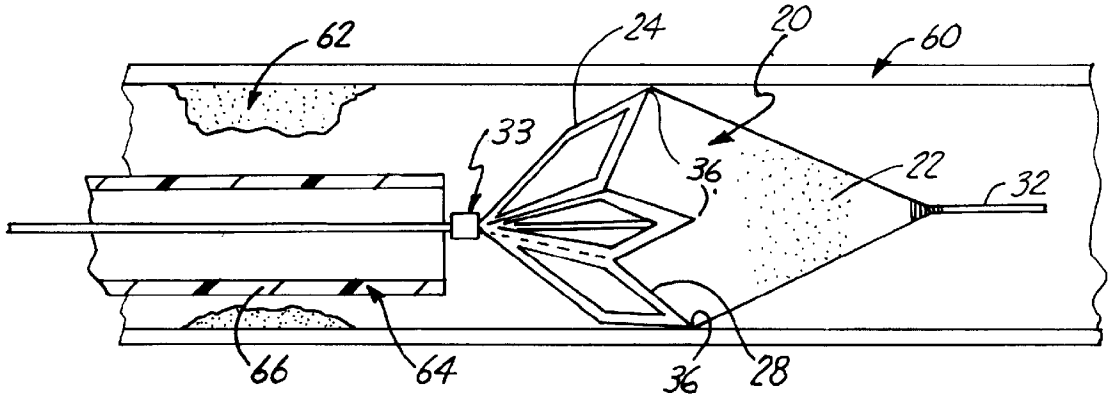


Fig. 6

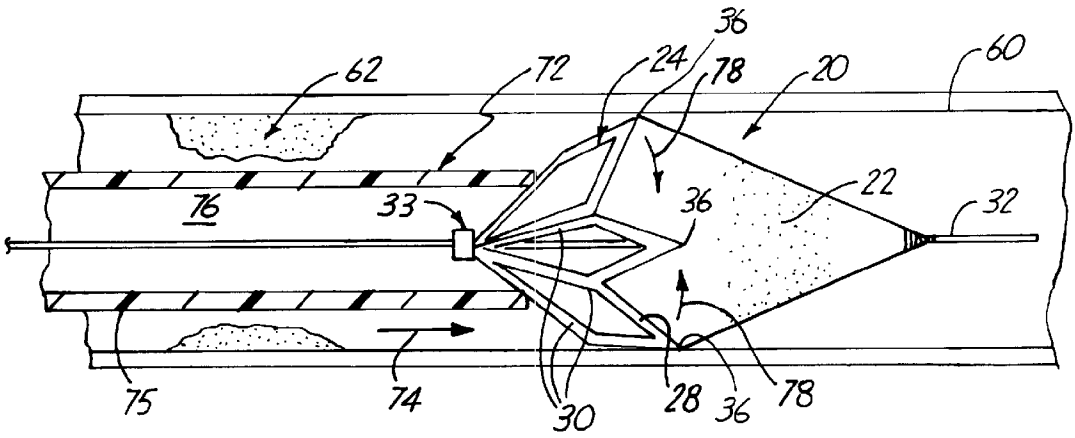

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Fig. 7

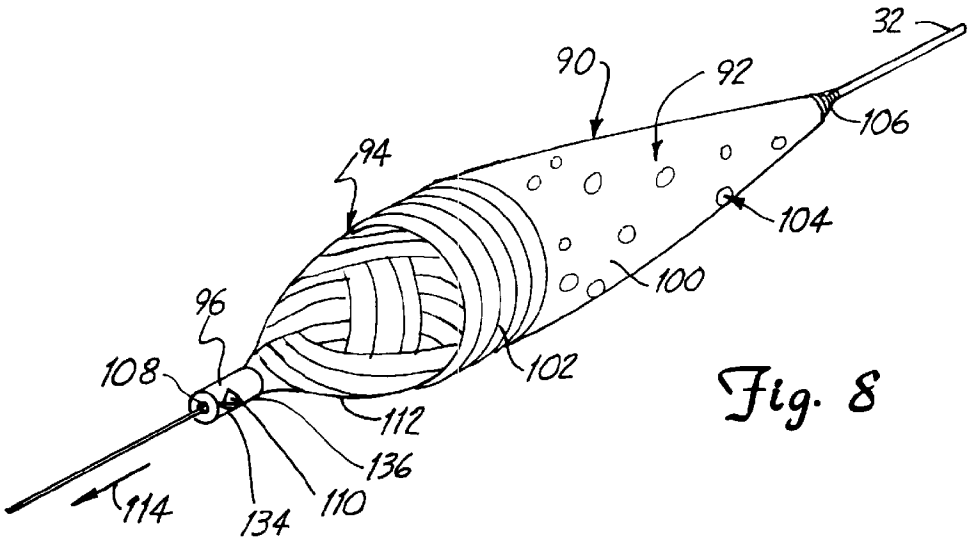
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Fig. 8

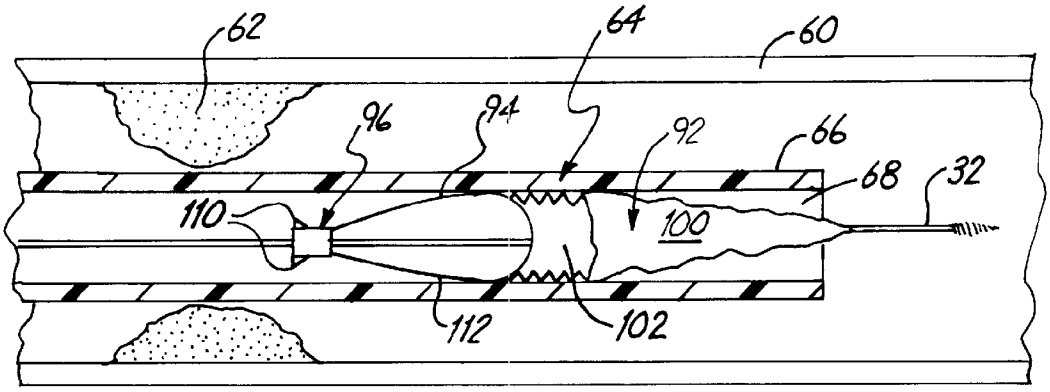
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Fig. 9

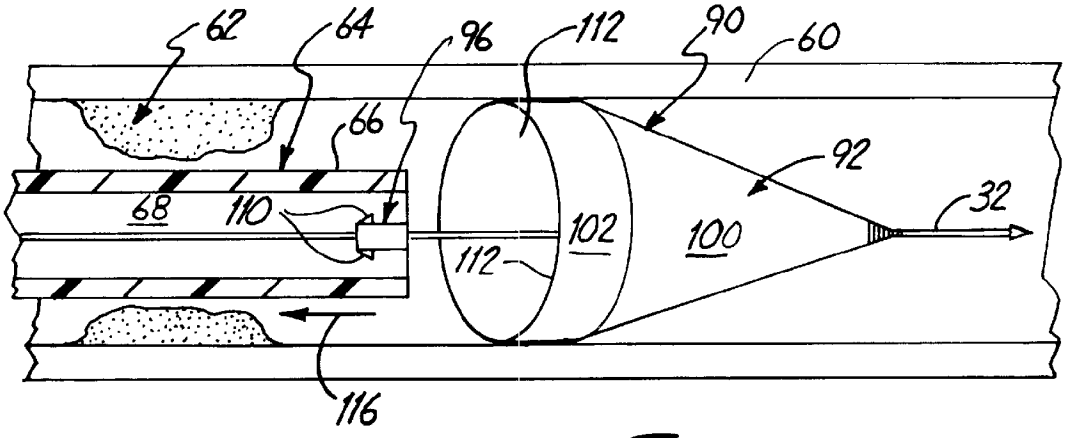
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Fig. 10

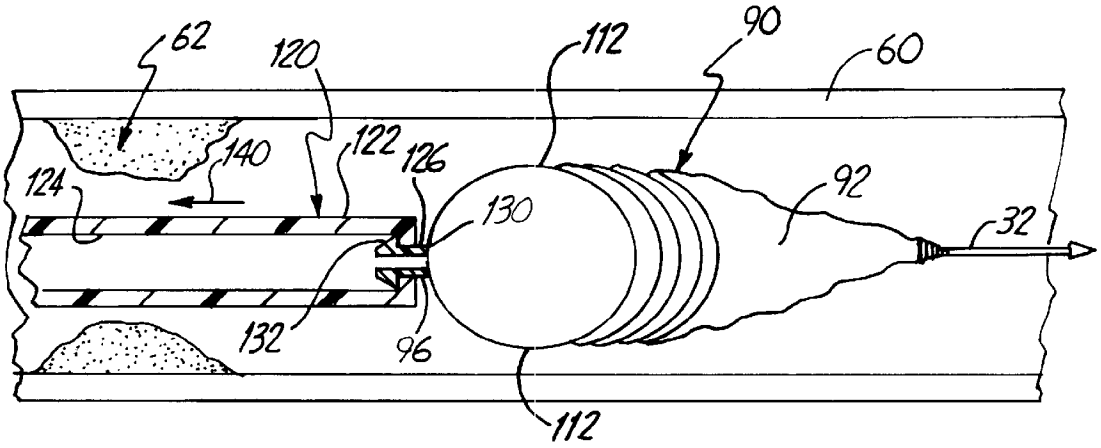
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Fig. 11

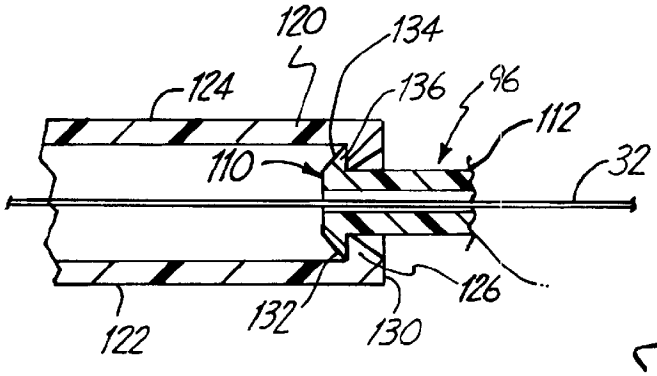
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Fig. 12

Fig. 13

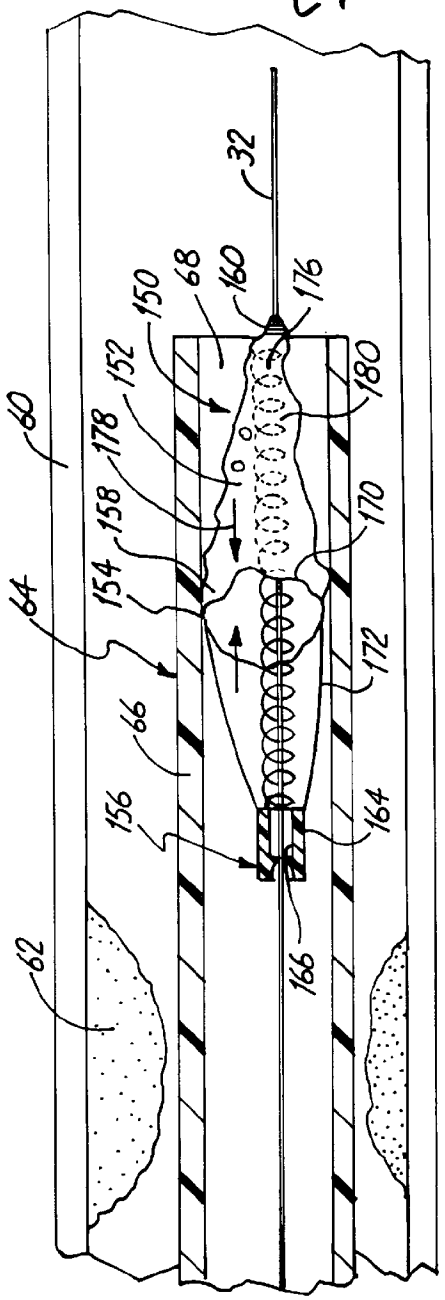
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Fig. 14

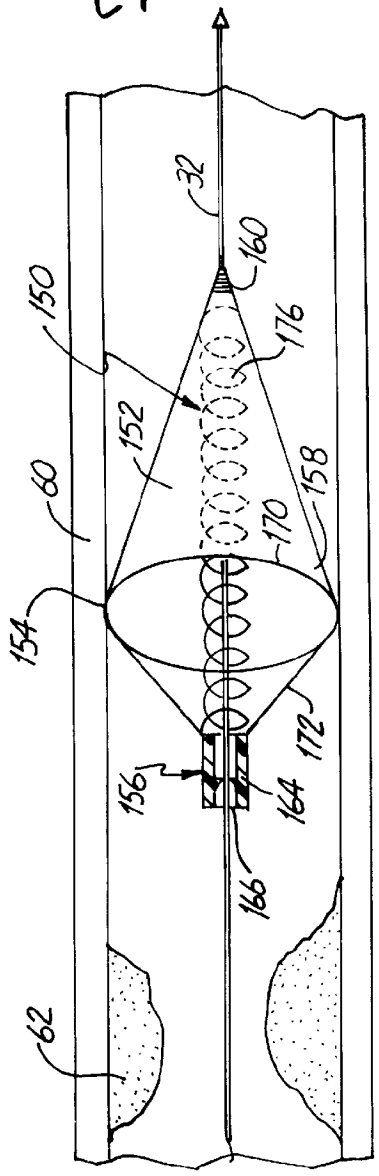
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Fig. 15

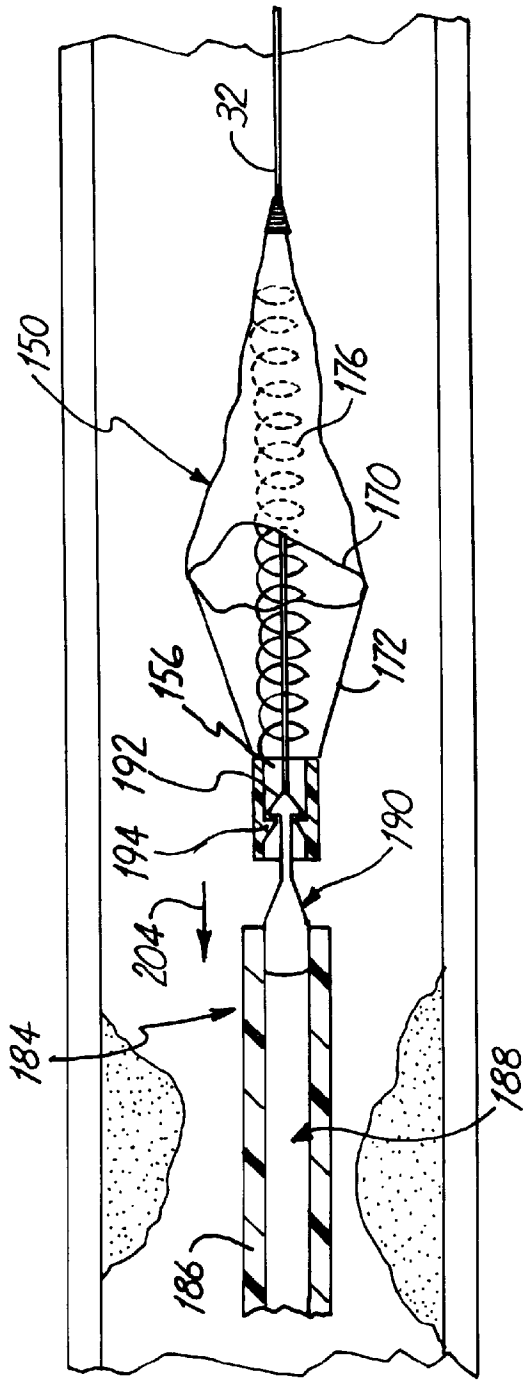
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Fig. 16

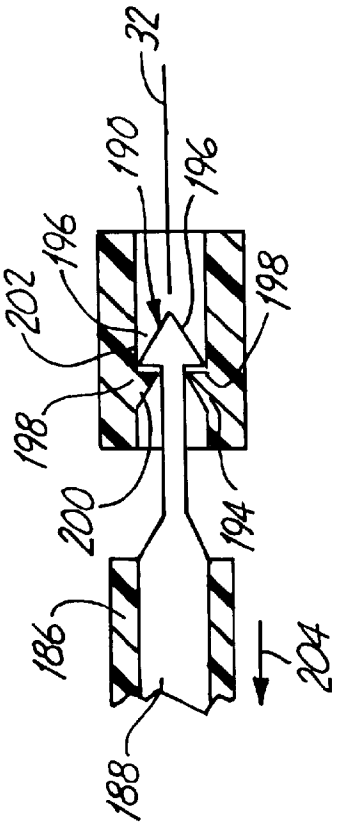
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Fig. 17

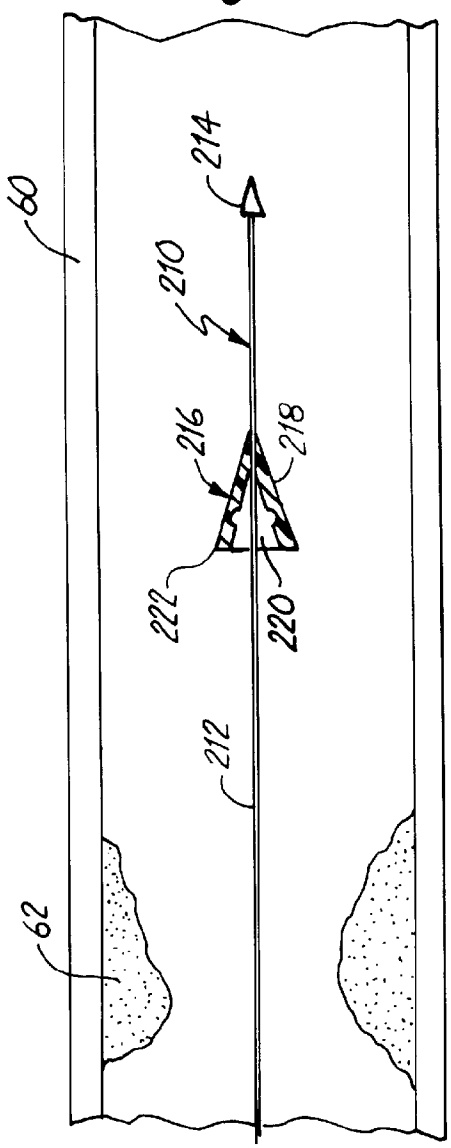
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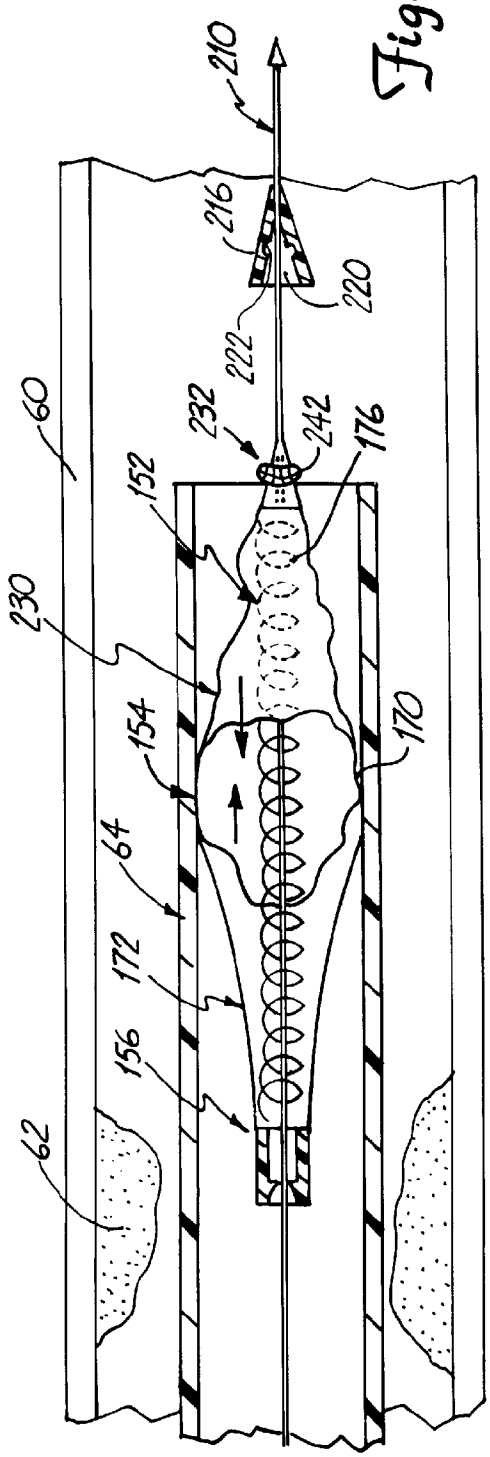
Fig. 18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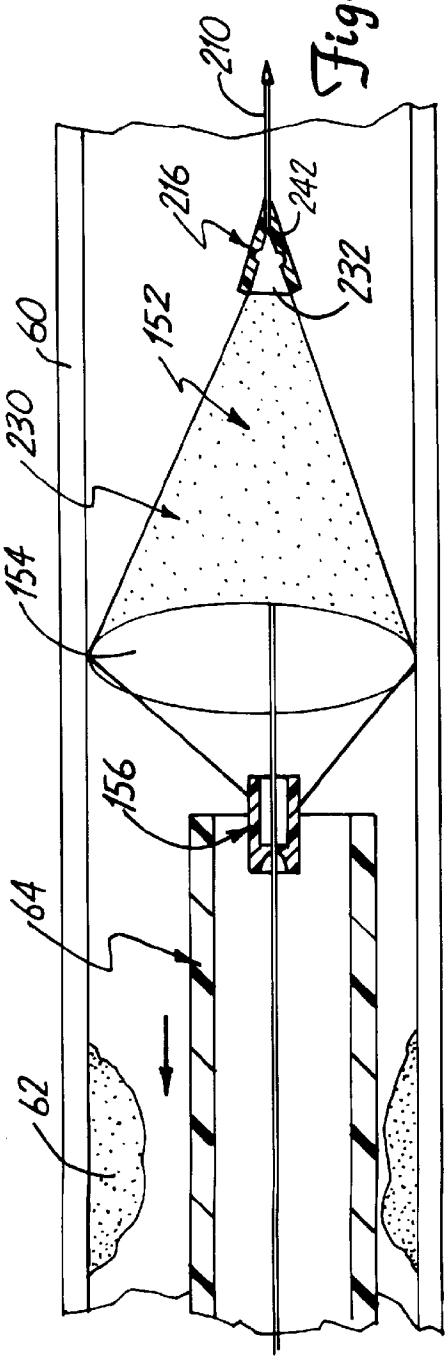
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Fig. 19

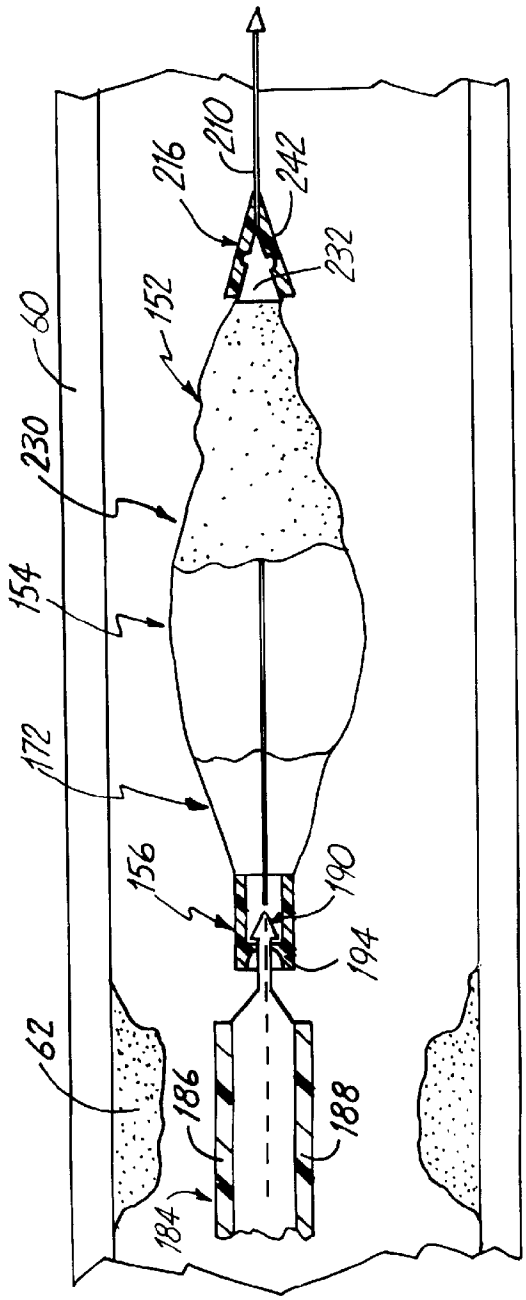
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Fig. 20

Fig. 21

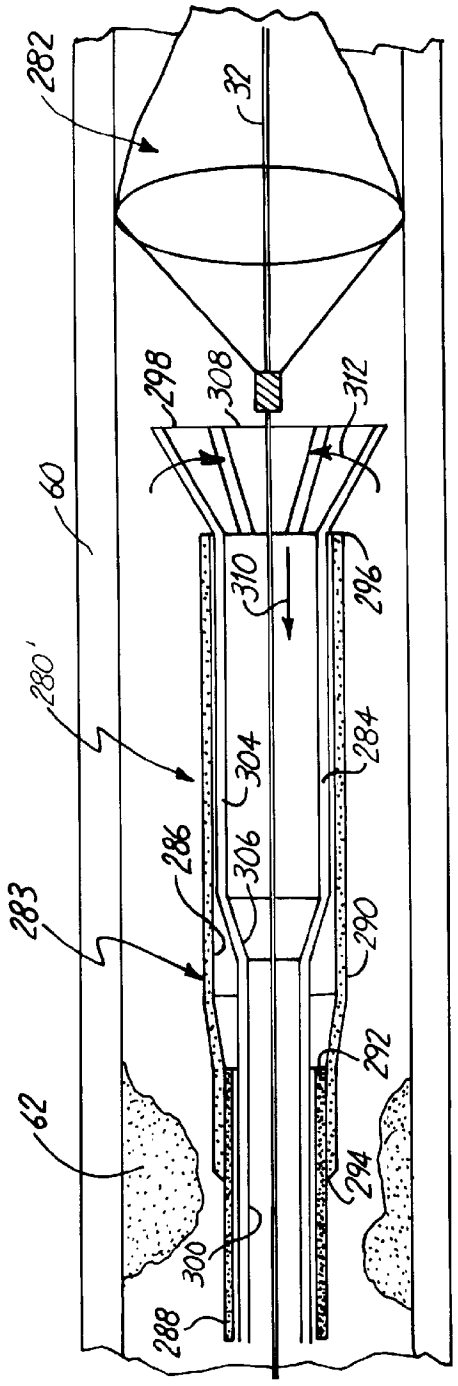
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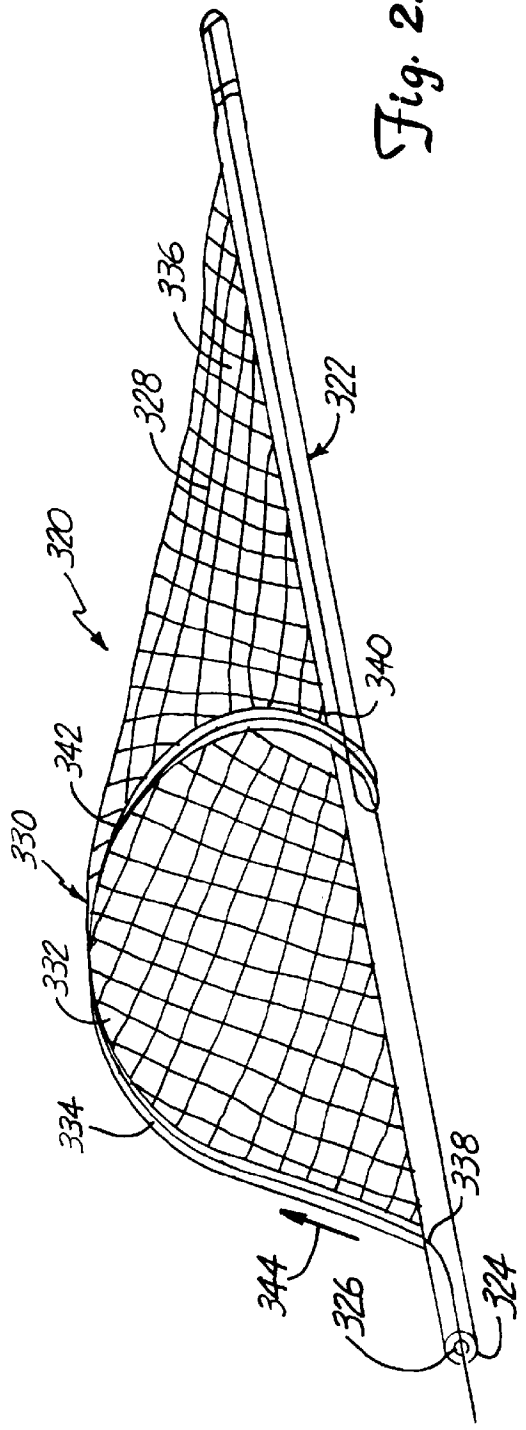
Fig. 22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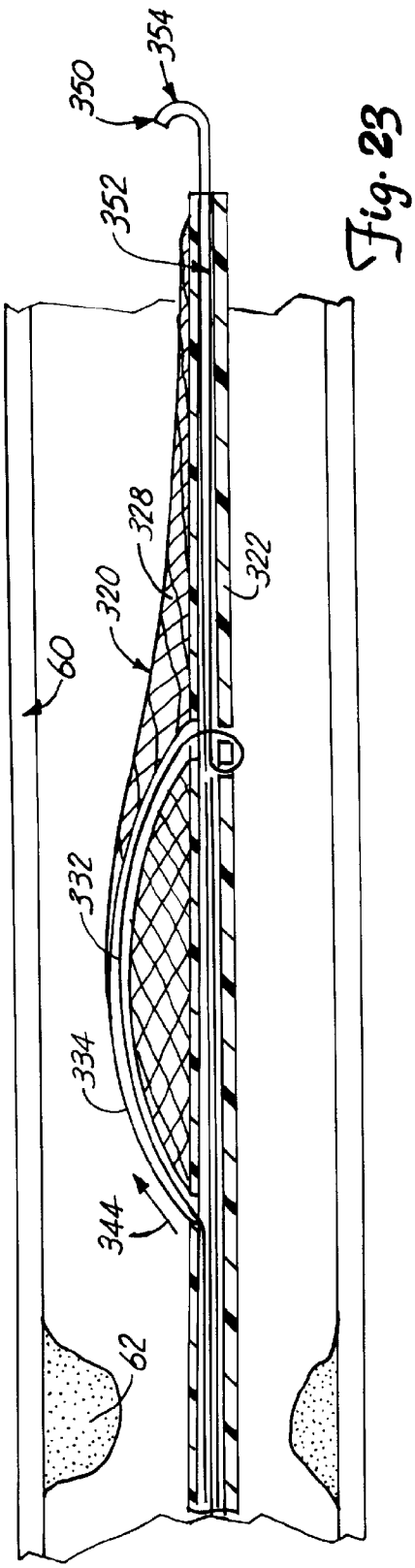
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Fig. 23

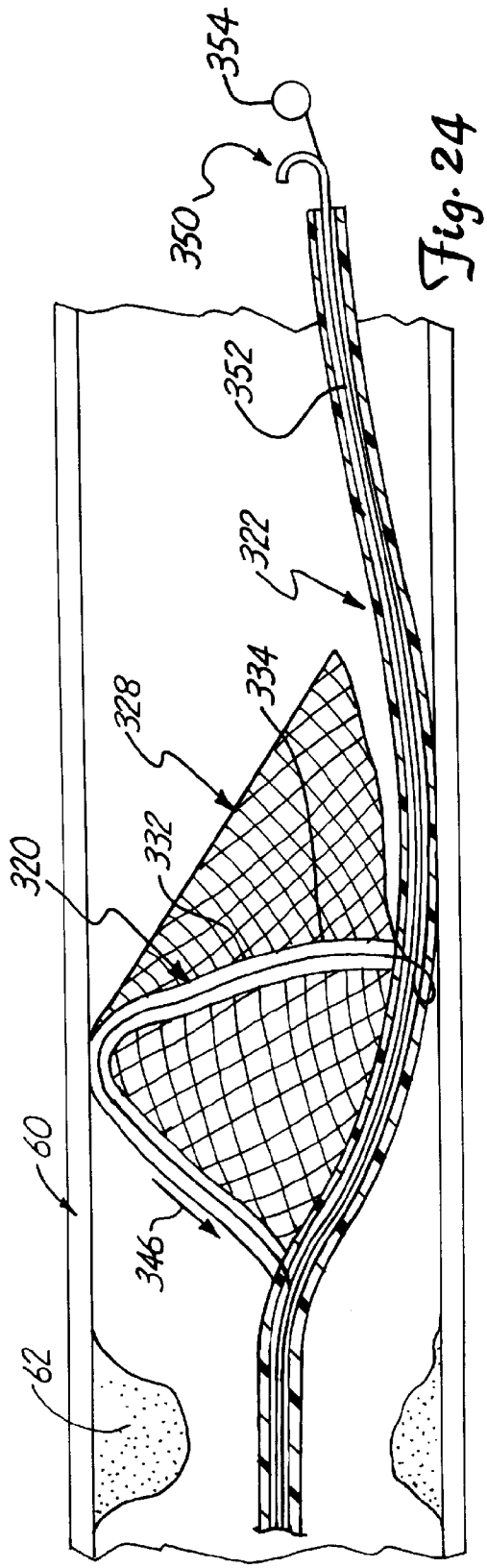
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Fig. 24

DISTAL PROTECTION DEVICE AND METHOD

CROSS-REFERENCE TO RELATED APPLICATION

This application claims priority to copending application Ser. No. 08/943,358, filed Oct. 3, 1997, now U.S. Pat. No. 6,001,118, entitled DISTAL PROTECTION DEVICE AND METHOD and assigned to the same assignee as the present invention, and application Ser. No. 08/810,825 filed Mar. 6, 1997, now U.S. Pat. No. 5,814,064, entitled DISTAL PROTECTION DEVICE and assigned to the same assignee as the present invention.

BACKGROUND OF THE INVENTION

The present invention deals with an emboli capturing system. More specifically, the present invention deals with an emboli capturing system and method for capturing embolic material in a blood vessel during an atherectomy or thrombectomy procedure.

Blood vessels can become occluded (blocked) or stenotic (narrowed) in a number of ways. For instance, a stenosis may be formed by an atheroma, which is typically a harder, calcified substance which forms on the lumen walls of the blood vessel. A stenosis may also be formed of a thrombus material, which is typically much softer than an atheroma but can nonetheless cause restricted blood flow in the lumen of the blood vessel. Thrombus formation can be particularly problematic in a saphenous vein graft ("SVG").

Two different procedures have been developed to treat a stenotic lesion (stenosis) in vasculature. One is deformation of the stenosis to reduce the restriction within the lumen of the blood vessel. This type of deformation, or dilatation, is typically performed using balloon angioplasty.

Another method of treating stenotic vasculature is to attempt to completely remove the entire stenosis, or enough of the stenosis to relieve the restriction in the blood vessel. Removal of the stenotic lesion has been performed through use of radio frequency ("RF") signals transmitted via conductors, and also through use of lasers. Both of these treatments are intended to ablate (i.e., super heat and vaporize) the stenosis. Removal of the stenosis has also been accomplished using thrombectomy or atherectomy. During thrombectomy and atherectomy, the stenosis is mechanically cut or abraded away from the vessel. However, problems may be encountered during thrombectomy and atherectomy because the stenotic debris which is separated from the stenosis is free to flow within the lumen of the vessel. If the debris flows distally, it can occlude distal vasculature and cause significant problems. If it flows proximally, it can enter the circulatory system and form a clot in the neural vasculature or in the lungs, both of which are highly undesirable.

Prior attempts to deal with the debris or fragments produced during thrombectomy and atherectomy have included cutting the debris into pieces small enough (having a size on the order of a blood cell) that they will not occlude vessels within the vasculature. However, this technique has certain problems. For instance, it is difficult to control the size of the fragments which are severed from the stenotic lesion. Larger fragments may be severed accidentally. Also, since thrombus is much softer than an atheroma, it tends to break up easier when mechanically engaged by a cutting instrument. Therefore, at the moment that the thrombus is mechanically engaged, there is a danger that it can be dislodged in large fragments which would occlude the vasculature.

Another attempt to deal with debris severed from a stenosis is to remove the debris as it is severed, using suction. However, it may be necessary to pull quite a high vacuum in order to remove all of the pieces severed from the stenosis. If the vacuum used is not high enough, all of the severed pieces will not be removed. Further, use of a high vacuum may tend to cause the vasculature to collapse.

A final technique for dealing with the fragments severed during atherectomy of the stenosis is placement of a device distal to the stenosis during atherectomy to catch the pieces of the stenosis as they are severed, and removal of those pieces along with the capturing device when the atherectomy procedure is complete. Such capture devices have included expandable filters which are placed distal of the stenosis to capture stenosis fragments. Problems are also associated with this technique. For example, delivery of such devices in a low-profile pre-deployment configuration can be difficult. Further, some devices include complex and cumbersome actuation mechanisms. Also, retrieving such capture devices, after they have captured emboli may be difficult.

SUMMARY OF THE INVENTION

The present invention provides a device adapted for deployment in a body vessel for collecting emboli. The device includes a proximally-tapered collapsible frame for operably supporting the filter between a collapsed insertion profile and an expanded deployment profile. The tapered frame includes a mouth which is sized to extend to walls of a body cavity in the expanded deployed profile for collecting emboli floating in the body cavity.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is a perspective view of an embodiment of a protection device in a radially-expanded deployed profile.

FIG. **2** is a view of the protection device of FIG. **1** in a somewhat collapsed profile.

FIG. **3** is an end view of the protection device of FIG. **1** in a radially-expanded deployed profile.

FIG. **4** is a plan view of a wire mesh sheet for construction of a frame of the protection device illustrated in FIG. **1**.

FIG. **5** is a view of the protection device of FIGS. **1–3** in a collapsed profile being inserted through a vessel via an insertion sheath.

FIG. **6**. is a view of the protection device of FIGS. **1–3** inserted into a vessel via the insertion sheath, where the insertion sheath is withdrawn to deploy the protection device for operation.

FIG. **7** is a view of the protection device of FIGS. **1–3** operating in a vessel in an expanded deployed profile and illustrating a retrieval sheath for withdrawal of the deployed protection device.

FIG. **8** is a perspective view of an alternate embodiment of a protection device shown in a radially-expanded deployed profile.

FIG. **9** is a view of the protection device of FIG. **8** in a collapsed profile, inserted into a vessel via an insertion sheath.

FIG. **10** is a view of the protection device of FIG. **8** in an expanded deployed profile in a vessel, shown with the insertion sheath withdrawn.

FIG. **11** is a view of the protection device of FIG. **8** in a somewhat collapsed profile being withdrawn from the vessel via a retrieval sheath.

FIG. **12** is a detailed view of portion **120** of the device shown in FIG. **11**.

FIG. **13** is a view of an alternate embodiment of a protection device in a collapsed profile being inserted into a vessel via an insertion sheath.

FIG. **14** is a view of the protection device of FIG. **13** in an expanded deployed profile in a vessel.

FIG. **15** is a view of the protection device of FIG. **13** in a collapsed profile being withdrawn from the vessel via a retrieval sheath.

FIG. **16** is a detailed view of portion **16** of the device shown in FIG. **15**.

FIG. **17** is a view of a guidewire adapted to support an alternate embodiment of a protection device.

FIG. **18** is a view of an alternate embodiment of a protection device in a collapsed profile, inserted into a vessel via an insertion sheath.

FIG. **19** is a view of the protection device of FIG. **18** in an expanded deployed profile in a vessel, shown with the insertion sheath withdrawn proximally.

FIG. **20** is a view of the protection device of FIG. **18** in a collapsed profile being withdrawn from the vessel via a retrieval sheath.

FIG. **21** illustrates an embodiment of a retrieval sheath for withdrawal of a protection device.

FIG. **22** is a perspective view of an alternate embodiment of a protection device, coupled to a guidewire in an expanded deployed profile.

FIG. **23** is a view of the protection device of FIG. **22** in a collapsed profile in a vessel.

FIG. **24** is a view of the protection device of FIG. **22** in an expanded deployed profile in a vessel.

These drawings are for illustrative purposes only and are not necessarily drawn to scale.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

The present invention relates to protection devices deployed in a body vessel or cavity for collection of loosened or floating debris such as embolic material dislodged during atherectomy or thrombectomy.

FIGS. **1–7** illustrate an embodiment of a protection device **20** or filter for collecting loosened debris in a body lumen. As illustrated comparatively in FIGS. **1–2**, device **20** operates between a closed collapsed profile, adapted for insertion into a body lumen as illustrated in FIG. **2**, and an open radially-expanded deployed profile for collecting debris in a body lumen as illustrated in FIG. **1**.

Device **20** includes a filter **22** and a collapsible proximally-tapered frame **24**. Frame **24** supports filter **22** and is operably coupled to an elongated guidewire **32** or other support device. Frame **24** includes a mouth **28** and a plurality of longitudinally-extending ribs **30**. In an expanded profile, mouth **28** is opened and the ribs extend radially outwardly to support mouth **28**. Preferably, a collar **33** movably couples the proximal ends of ribs **30** to guidewire **32**. Mouth **28** is thus coupled to collar **33** through ribs **30** and is movable between a collapsed profile and an opened deployed profile, as will be explained.

Preferably, filter **22** is generally cone-shaped, having a proximal and a distal end. The distal end is a narrow, "V"-shaped end and is preferably fixedly secured or formed to guidewire **32**. The proximal end has a relatively wide opening and is coupled to mouth **28** of frame **24**. Preferably, filter **22** is formed of a polymer membrane. In particular, filter **22** is preferably formed of a porous polyurethane material having a plurality of small openings **40**. Filter **22** may be constructed of a polyurethane sheet, and openings **40** may be formed in the polyurethane sheet by known laser techniques. Holes or openings **40** are sized to allow blood flow therethrough but restrict flow of debris or emboli floating in the body lumen or cavity. In the embodiment shown, guidewire **32** extends through mouth **28** of device **20** and along the entire length of the device and is fixed to the distal end of filter **22**.

Mouth **28** is generally formed of a pleated ring **34** having an expanded dimension to support filter **22** in the opened deployed profile as illustrated in FIGS. **1–3**, and a collapsed dimension to support the filter in the closed collapsed profile as illustrated in FIG. **2**. FIG. **3** is an end view of device **20** which illustrates pleated ring **34** in an open expanded profile. In the opened expanded profile, ring **34** includes a plurality of folds **36** which are spaced so that the diameter of the pleated ring **34** forms a mouth of sufficient diameter so that an opening to filter **22** conforms to a desired body lumen. Pleated ring **34** is collapsed by closing folds **36** as illustrated by arrows **38** so that adjacent folds **36** are positioned in close proximity. In such a position, the mouth assumes a relatively small dimension to collapse filter **22** for insertion and retrieval. As previously explained, pleated ring **34** is coupled to guidewire **32** via ribs **30** as shown in FIG. **3**.

FIG. **4** illustrates a process of forming frame **24** and folds **36**. Frame **24** may be formed from a wire mesh sheet **42** having a series of rows of generally diamond-shaped structures **44**. In one preferred embodiment, a portion **46** of a row is cut from wire mesh sheet **42** to form the frame **24**. Portion **46** is rolled and sides **50, 52** are joined to form a continuous circular frame. A series of tips **54** on a first end are joined and coupled to ring **33** which slides over guidewire **26**. A series of tips **56** on the second end form pleated ring **34** of mouth **28**. In particular, tips **56** form the apex of folds **36**, which expand and collapse as illustrated by arrows **38** in FIG. **3**, to open and close mouth **28**. Preferably, the wire mesh sheet **42** is formed of Nitinol or similar material having sufficient elasticity or resilience, as will be explained. The proximal end of filter **22** is then secured to mouth **28** via an adhesive or other suitable connection method. The distal end of filter **22** is then secured to guidewire **26** via adhesive or other techniques.

FIGS. **5–7** illustrate operation of protection device **20** which is inserted into a body lumen to collect floating debris or emboli. Briefly, as shown in FIG. **5**, device **20** is inserted into a body lumen **60**, such as a vascular lumen having a stenosis **62**. Device **20** may be deployed distal of the blocked region or stenosis **62** to capture calcified material or substances dislodged during a medical procedure to open the stenosis **62**. The stenosis **62** in a coronary vessel may be opened by known medical procedures such as dilatation or atherectomy.

More specifically, as shown in FIG. **5**, device **20** is first collapsed and inserted in the collapsed profile into a delivery sheath **64**. Sheath **64** is formed of a tubular member **66** including an inner lumen **68** extending therethrough. The profile of sheath **64** is relatively small to facilitate insertion and placement of device **20**. Device **20** is placed in lumen **68** for insertion. Folds **36** of frame **24** are collapsed and are maintained in the collapsed profile by the inner surface of lumen **68**. In the collapsed profile, collar **33** slides proximally along guidewire **32** to accommodate for the proximal longitudinal movement of ribs **30** as device **20** is collapsed. Once device **20** is inside delivery sheath **64**, sheath **64** is

inserted through the vasculature of a patient and has its distal end positioned distal of the stenosis or blocked region **62**.

To deploy device **20** after it is suitably located, sheath **64** is withdrawn as illustrated by arrow **70** in FIG. **6**, thus releasing the pressure exerted via the tube **66** to maintain frame **24** in the collapsed profile. Thus, folds **36** resiliently separate to open mouth **28** and the filter **22** for operation, as illustrated in FIG. **6**. Mouth **28** is sized so that when folds **36** separate, mouth **28** conforms to the dimensions of vascular lumen **60**. Mouth **28** supports filter **22** relative to the circumference of vascular lumen **60** so that blood flows through the filter and debris and particles floating in the blood are trapped by the filter. In particular, holes **40** of the filter allow blood to flow therethrough, but restrict flow of debris and clotting material so that loosened debris does not migrate and clog alternate body sites.

Preferably, as previously explained, frame **28** is formed of a Nitinol alloy or other elastic material so that the frame "springs" back to an expanded profile after the confining force imparted via sheath **64** is released. The relatively elastic material provides sufficient resilient force for a tight interaction between mouth **28** and lumen **60** to assure that blood flows through filter **22** to capture floating debris and particles.

After deployment, sheath **64** may be completely withdrawn and various treatment devices, such as an angioplasty dilatation catheter, stent delivery catheter or other atherectomy or thrombectomy devices, may be inserted for treatment. The treatment devices are inserted over guidewire **32** for placement relative to the treatment site. After treatment is complete, device **20** is removed as illustrated in FIG. **7**.

As shown in FIG. **7**, a retrieval sheath **72** is inserted as illustrated via arrow **74** for removal of device **20**. Retrieval sheath **72** is formed of a tubular member **75** having a central lumen **76** and a distal opening sized to capture device **20**. Retrieval sheath **72** is inserted to align the distal opening of sheath **72** with the proximal end of frame **24**. Thereafter, sheath **72** is advanced; or, alternatively, in the embodiment shown, guidewire **32** is retracted, to collapse ribs **30**, thereby collapsing mouth **28** and filter **22** as illustrated by arrows **78**. In particular, ribs **30** (and the frame **24**) are proximally sloped or tapered so that as sheath **72** is advanced over ribs **30**, they collapse radially inwardly and collar **33** rides proximally on guidewire **32**. As ribs **30** collapse inwardly, frame **24** folds at folds **36** until mouth **28** resides within retrieval sheath **72**, or closely proximate the distal end of sheath **72**, thereby trapping emboli therein. Device **20** and sheath **72** are then withdrawn from the vasculature.

Although longitudinally sloped ribs **30** are coupled to collar **33** in the device shown, ribs **30** may be directly fixed to guidewire **32** so that the filter is loosely supported in the collapsed profile. Alternatively, the device may be supported via an alternate core wire or guidewire structure (not shown) which is coupled to frame **24** via ribs **30** but unlike guidewire **32** does not extend through the mouth and along the entire length of the filter so that device **20** does not have radial slack in the collapsed profile. Also, although device **20** is shown inserted distal of stenotic region **62** to capture material and debris dislodged during a treatment procedure, device **20** may be deployed in alternate positions for capturing floating debris or particles in other body cavities.

FIGS. **8–11** illustrate an alternate embodiment of a protection device **90**. As illustrated in FIG. **8**, protection device **90** includes a filter **92**, a frame **94** and a collar **96**. Protection device **90** is operably coupled to a guidewire **32** for operation as will be explained. Guidewire **32** is a typical guidewire having a small diameter for insertion into a tract to a treatment site, and preferably includes a spring coil tip.

Filter **92** includes a cone-shaped porous portion **100** and a pleated portion **102**. Porous portion **100** includes a plurality of openings **104** to permit blood flow through filter **92** while restricting flow of debris or particles. A distal tip **106** of filter **92** is fixedly secured to guidewire **32**. Preferably, filter portion **100** is formed of a polymer material, such as a polyurethane material, and holes or openings **104** are formed via known laser techniques.

Collar **96** is preferably formed of a relatively short tubular member having an inner lumen **108** and having notches **110** formed on an outer perimeter. Guidewire **32** extends through lumen **108** so collar **96** is slidably coupled to guidewire **32**. Frame **94** is coupled to collar **96**, and filter **92** is coupled to frame **94**.

Preferably, frame **94** is formed of an elongated wire **112** having opposed ends. Opposed ends of wire **112** are coupled to collar **96** to form a mouth, and filter **92** (in particular, pleated portion **102**) is coupled to wire **112** along substantially the entire length of wire **112**. Preferably, guidewire **32** extends through collar **96** and through the mouth and extends along the entire longitudinal length of filter **92**. Thus, collar **96** is moved proximally as illustrated by arrow **114** to collapse the mouth formed by frame **94** for insertion. Collar **96** is slid distally to expand the mouth formed by frame **94** and filter **92** to a deployment position.

Preferably, wire **112** is formed of a relatively elastic material such as Nitinol. Filter portion **102** is secured to wire loop **112** by one of various suitable attachment methods, including adhesives, stitching, or other known methods, to define the mouth of the device **90**. Ends of wire **112** are also preferably coupled to collar **96** by known attachment methods, including adhesives.

Preferably, pleated filter portion **102** is formed of a polymer material such as polyurethane. The pleated filter portion **102** is preferably manufactured by winding a wire or other suitable coil around a polymer tube material. After the wire is wound around the tube, the tube is pressurized, causing the tube material to expand between the gaps in the wire, creating the pleats or creases which allow portion **102** to collapse. The coil is then removed, leaving collapsible portion **102**. Construction of collapsible portion **102** is described in St. Germain, U.S. Pat. No. 5,534,005, issued Jul. 9, 1997, and assigned to Scimed Life Systems, Inc., hereby incorporated by reference.

The pleated filter portion **102** allows for the filter to expand or extend longitudinally to absorb impact pressure caused by embolic material received by filter portion **92** to maintain the placement of the device **90** during operation. Filter portion **100** and pleated portion **102** may be formed separately or from a single sheet of polymer material.

FIGS. **9–12** illustrate operation of device **90** in a patient's vasculature. Some parts are similar to those shown in FIGS. **5–7**, and similar numbers are used to identify similar parts. As shown in FIG. **9**, device **90** is inserted in a collapsed profile in cooperation with an insertion sheath **64** similar to that shown and described in FIG. **5**. Tube **66** exerts a force on wire **112** and filter portions **100**, **102** to collapse device **90**. As illustrated, in the collapsed profile, collar **96** moves along wire **32** to longitudinally accommodate for radial slack of the collapsed device **90**. Sheath **64** and device **90** are advanced to a deployment site, preferably distal of a stenotic region **62**, for operation during a treatment procedure.

Once device **90** and sheath **64** are located at the deployment site, sheath **64** is withdrawn (while the position of

guidewire **32** is maintained) as illustrated by arrow **116** so that the wire **112** expands radially outwardly (since the compression force is released). This causes filter **92** to expand to conform to the inner diameter of the vessel **60**. As wire **112** expands outwardly, collar **96** slides distally along guidewire **32** for radial expansion of wire **112** and filter **92**. Preferably, as previously explained, wire **112** is formed of a sufficiently elastic material to essentially spring outwardly after pressure is released, so that a tight interference between frame wire **112** and the vessel walls of vessel **60** is maintained. This helps to ensure that the device **90** is sufficiently lodged against vessel wall **60** so that it stays in position during treatment and is not dislodged as a result of blood flow through the filter **92**. In particular, sufficient pressure must be maintained so that the filter conforms to the diameter of vessel **60** and does not migrate due to force imparted to the filter when debris collects in the filter and so that no embolic material can slip between the filter and the walls of vessel **60**.

Thereafter, treatment devices (not shown) may be advanced along guidewire **32** for placement relative to a stenosis **62** for treatment. Such treatment devices may include a dilatation catheter, stent delivery catheter or atherectomy or thrombectomy devices, etc. After treatment is completed, device **90** may be withdrawn as illustrated in FIGS. **11** and **12**. Device **90** is withdrawn via a retrieval device **120**. Retrieval device **120** is formed of a tubular member **122** having an inner lumen **124** and a locking tab **126** formed on an inner surface of the tubular member **122**. Locking tab **126** mates with notch **110** formed on collar **96** for retrieval and removal of device **90**.

Preferably, locking tab **126** is formed of a rigid extension having a sloped camming surface **130** and a flat locking surface **132**. Notch **110** also includes a camming surface **134** and a flat locking surface **136**. The camming surfaces **130**, **134** are aligned so that, as sheath **120** is advanced, camming surfaces **130**, **134** mate to slightly expand tube **122** so that locking member **126** on sheath **120** advances past notch **110** until the locking surfaces **132**, **136** align and the camming force is released. This allows tube **122** to collapse to its original dimension with surfaces **132**, **136** aligned to lock device **90** to sheath **120** for withdrawing device **90**. Sheath **120** is withdrawn proximally, as illustrated by arrow **140**, while maintaining the position of guidewire **32**. This causes collar **96** to slide proximally to collapse device **90** along guidewire **32** thereby drawing wire **112** down over wire **32** and collapsing device **90**. Once device **90** is collapsed, guidewire **32** and sheath **120** are collectively withdrawn to remove collapsed device **90**.

FIGS. **13–16** illustrate an alternate embodiment of a protection device **150** where similar numbers are used to identify similar parts of previous embodiments. Device **150** is shown in operation in a vessel **60** having a stenosis **62**. Device **150** includes a filter **152**, a frame **154**, and a collar **156**. Device **150** is operably coupled to guidewire **32** for operation. Filter **152** is preferably a cone-shaped member having proximal and distal ends **158**, **160**. The distal end **160** is generally "V"-shaped. Filter **152** may be formed from a polymer sheet material similar to that described for previous embodiments and filter holes or openings **180** may be formed therein by laser techniques. Material and debris generally collect at the "V"-shaped tip to limit interference with blood flow through filter **152**. The "V"-shaped end **160** is fixedly coupled relative to guidewire **32**. Proximal end **158** includes an opening which is supported relative to frame **154** to form a mouth of the device, as will be explained. Collar **156** is a tubular member **164** having an inner lumen **166** slidably coupled relative to guidewire **32**.

Frame **154** includes a generally circular mouth member **170** and a plurality of struts or ribs **172**. Mouth **170** supports filter **152** and is preferably formed of a wire loop which is coupled thereto via a known adhesive or other suitable means. The mouth is coupled to collar **156** via struts or ribs **172** so that the collar slides along guidewire **32** to selectively longitudinally extend device **150** to collapse device **150** for insertion and retrieval, and longitudinally shorten device **150** to expand device **150** (and mouth **170**) for deployment. Preferably, struts **172** are attached to collar **156** and mouth **170** by any suitable means. Preferably, frame **154** (mouth **170** and struts or ribs **172**) are formed of a wire or strip of a relatively elastic material such as a Nitinol material.

Device **150** includes compression spring **176** to bias device **150** in the longitudinally shortened (and thus radially expanded) profile having mouth **170** radially expanded for operation. In particular, spring **176** includes opposed ends, a first end is attached to collar **156**, and a second end is attached to end **160** of filter **152**. The compression spring **176** is normally biased to compress as illustrated by arrows **178** to bias the device in an opened deployed profile.

For insertion, device **150** is maintained in a low-profile position via sheath **64** as illustrated in FIG. **13** similar to that described for previous embodiments. In particular, sheath **64** exerts a force on frame **154** and filter **152** to compress frame **154** and filter **152** against the spring bias provided by compression spring **176**. As shown in FIG. **13**, insertion sheath **64** and device **150** are inserted into a patient and located distal of a stenosis **62** for deployment.

To deploy the device, the sheath **64** is withdrawn while the operator maintains the position of guidewire **32**. Once sheath **64** is withdrawn from device **150**, frame **154** and filter **152** expands radially outwardly under the force of the compression spring **176** to expand mouth **170** to conform to the vessel walls **60** as illustrated in FIG. **14**. Ribs **172** are extended outwardly to support mouth **170** in a radially-expanded position. The spring **176** maintains device **150** in a deployed position so that mouth **170** conforms to the opening of the vessel. Debris is captured and device **150** does not migrate under the load of the debris collected in filter **152**.

After treatment is completed, device **150** may be withdrawn. Preferably, device **150** is withdrawn via a removal sheath **184** , as illustrated in FIGS. **15–16**. The removal sheath **184** includes an outer tubular extent **186** supporting an inner tube **188**. The inner tube **188** includes a docking tip **190**. Docking tip **190** includes docking latch **192** which cooperate with a latch **194** formed on an inner surface of collar **156**. Docking latch **192** is formed of an arrow tip **190** defining sloped camming surface **196** and a lateral locking surface **198**. Latch **194** on collar **156** includes a camming surface **200** and a lateral locking surface **202**.

Sheath **184** is advanced over the guidewire **32** to insert tip **190** through the opening in tubular collar **156**. Tip **190** is advanced until camming surfaces **196**, **200** expand collar **156** to further advance arrow-shaped tip **190** until collar **156** collapses to align locking surfaces **198**, **202** to lock device **150** to sheath **184** for withdrawal. After device **150** is locked to sheath **184**, retrieval device **184** is first withdrawn proximally, as illustrated by arrow **204**, while maintaining the position of guidewire **32** to force the frame **154** and filter **152** against the spring bias to a low-profile dimension. Thereafter, retrieval sheath **184** and guidewire **32** are collectively proximally withdrawn as illustrated to remove the device.

An alternate embodiment of a protective device is illustrated in FIGS. **17–20** and is formed independently of a

guidewire **210**. Guidewire **210** is formed of an elongated wire **212**, preferably having a spring coil tip **214**, and a protective device docking member **216** coupled to a distal portion of wire **212**, as illustrated in FIG. **17**. Docking member **216** is rigidly coupled to wire **212** and in one embodiment is formed of a generally "V"-shaped member **218** including a docking channel **220**. Member **218** includes groove **222** which opens to channel **220**. Docking member **216** is used to removably secure a protection device thereto as will be explained.

Docking member **216** may be permanently formed on the guidewire **210**. Alternatively, docking member **216** may be detachably connected to guidewire **210** such as by a friction fit between guidewire **210** and a channel (not shown) of the docking member **216** or by a mechanical attachment mechanism. If a detachable, docking member **216** may be used on any suitable guidewire, thereby adapting the guidewire for operation with a protection device.

FIG. **18** illustrates an embodiment of a protection device **230** which may be selectively coupled to docking member **216**. Protection device **230** includes a distal cone **232**, a filter **152**, a frame **154**, and a collar **156**. Cone **232** is coupled to a distal end of filter **152**. Cone **232** is generally "V"-shaped and is formed of a rigid member having a distal opening (not shown) sized for insertion of guidewire **210** therethrough. Cone **232** includes a locking ring **242** extending about an outer perimeter of cone **232**. Locking ring **242** is sized for insertion into groove **222** of docking member **216**.

Thus, device **230** is mounted relative to the guidewire by inserting guidewire **210** through an opening in cone **232**. Device **230** is advanced over guidewire **210** to align cone **232** with docking member **216**. Cone **232** is forced into channel **220** of docking member **216** until ring **242** snaps into groove **222** and is maintained therein. Device **230** is inserted in a low-profile collapsed condition via cooperation with sheath **64**, and is deployed by withdrawing sheath **64** while maintaining the position of guidewire **210** after device **230** is positioned at a treatment site (as comparatively illustrated in FIGS. **18–19**) similar to that previously described with reference to FIGS. **13–14**.

FIG. **20** illustrates withdrawal of device **230** via retrieval sheath **184**, as previously described with reference to FIGS. **15–16**. Sheath **184** is coupled to collar **156** and is then withdrawn proximally while maintaining the position of guidewire **210** to collapse device **230** to a low profile. Thereafter, sheath **184** and guidewire **210** are withdrawn to remove guidewire **210**, protection device **230**, and sheath **184** from the patient after treatment.

FIG. **21** illustrates an embodiment of a retrieval sheath **280** for operation with a distal protection device **282** for collapsing the distal protection device for withdrawal. The retrieval sheath **280** includes a telescoping tubular structure including an outer tubular member **283** and an inner tubular member **284**. Outer tubular member **283** includes a lumen **286**, and inner tubular member **284** extends through lumen **286** and is movable therein to form the telescoping tubular structure.

Outer tubular member **283** is formed of a composite structure including a first tubular portion **288** and a second tubular portion **290**. The first tubular portion **288** includes a proximal end (not shown) and a distal end **292**. The second tubular portion **290** includes a proximal end **294** and a distal end **296**. Proximal end **294** is coupled to distal end **292** of tubular member **288** to form a composite outer tubular structure **283** having a proximal end (not shown) and distal end **296**.

Inner tube **284** includes a proximal end (not shown) and a distal end **298**. Inner tube **284** includes a first diameter portion **300**, a second diameter portion **304**, a transition portion **306**, and tapered flanged end **308**. First and second portions **300**, **304** are coupled via transition portion **306**. Flanged end **308** has a relatively large tapered mouth for capturing and progressively collapsing a deployed protection device as will be explained.

The proximal end of inner tube **284** extends through outer tube **283** and exits from proximal end of outer tube **283** for providing a mechanism for slidably moving inner tube **284** within outer tube **283**. Flanged end **308** is relatively flexible and resilient and is biased in a radially expanded position so that it opens to an expanded tapered profile, as illustrated in FIG. **21**, when flanged end **308** extends beyond distal end **296** of outer tube **283**. When flanged end **308** is retracted within inner tube **283** as illustrated via arrow **310**, flanged end **308** collapses as illustrated by arrows **312** to assume the dimension of outer tube **283** in a collapsed position (not shown). Flanged end **308** may be formed of a pleated material or simply a relatively elastic material.

In operation, retrieval sheath **280** is inserted into a patient's vasculature with flanged end **308** in a collapsed position within inner tube **283** to provide a low profile for insertion. Retrieval sheath **280** is inserted and aligned closely proximate to deployed protection device **282**. Once retrieval device **280** is aligned, inner tube **284** is slid distally relative to outer tube **282** to expand flanged end **308** to an expanded profile, as illustrated in FIG. **21**, to surround the deployed protection device. Thereafter, sheath **280** may be advanced, or protection device **282** may be withdrawn proximally via guidewire **32** to forcibly collapse protection device **282** as protection device **282** is withdrawn along the tapered inner channel of flanged end **308**. Retrieval device **280**, protection device **282**, and guidewire **32** are then withdrawn. The device thus provides a system for capturing a protection device **282** and filtered contents (debris, emboli, etc.) along therewith to minimize post-procedural embolic events. Preferably, inner and outer tubes **282**, **284** are formed of a polymer material, and flanged end **308** is formed of a polymer membrane. Although a particular embodiment of retrieval device **280** is shown, it should be understood that construction of device **280** is not limited to the exact construction shown.

FIGS. **22–24** illustrate an alternate embodiment of a distal protection device **320**. As shown in FIG. **23**, distal protection device **320** is coupled to a guidewire **322** to operate between a radially-expanded deployed profile illustrated in FIGS. **22** and **24**, and a collapsed profile illustrated in FIG. **23** for insertion and retrieval. Guidewire **322** is formed of a tubular member **324** including a central lumen **326** therethrough. The guidewire **322** may be formed of a hypo tube or other material. The distal protection device **320** includes a filter **328** and a frame **330**.

Preferably, frame **330** is formed of an elongate wire **332** and a polymer sleeve **334**. Frame **330** is coupled to guidewire **322** and is supported thereby between the insertion dimension illustrated in FIG. **23** and the deployed dimension illustrated in FIGS. **22** and **24**. Filter **328** is coupled to frame **330** and is supported thereby at its proximal end by frame **330**. Filter **328** may be formed of a polymer sheet material or a mesh-like material having holes or openings **336** therein to allow blood to flow therethrough while restricting flow of emboli, debris and clotting material. Filter **328** is cone-shaped, preferably having a "V"-shaped tip and a large opening to funnel debris for collection. Filter **328** and sleeve **334** may be integrally or separately formed, and secured via known attachment methods such as known adhesives.

Guidewire **322** includes spaced distal openings **338**, **340** which communicates with inner lumen **326**. Opposed ends of sleeve **334** are coupled to spaced openings **338**, **340** so the lumen through sleeve **334** forms a path for frame wire **332**. Frame wire **332** extends from a proximal end (not shown) of the guidewire **322** through lumen **326**, through openings **338** and **340**, and is anchored at a distal end of lumen **326** (preferably proximate to opening **340**). Frame wire **332** also extends through sleeve **334** to form an external loop **342** defining the mouth of the protection device **320**. External loop **342** is tightened by pulling the wire **332** proximally, and is opened by pushing the wire **332** distally, as illustrated by arrow **344**, to open and close the mouth of protection device **320**.

FIGS. **23–24** illustrate operation of protection device **320**. As illustrated in FIG. **23**, the device is inserted in a low-profile dimension by proximally retracting wire **332** to close external loop **342** to locate device **320** at a deployment site, preferably distal of a stenosis **62**. Frame wire **332** is moved distally as illustrated by arrow **344** to expand loop **342** to open the mouth to filter **328** to conform to the dimension of vascular lumen **60**, as illustrated in FIG. **24**. As the mouth of the device **320** is expanded to conform to the vascular dimension, guidewire **322** pushes against a lumen wall to provide a tight fit between filter **328** and vascular wall **60**.

The mouth has a dimension which conforms to the vascular wall, and cone-shaped filter **328** funnels material to a tip of the filter to allow bloodflow to continue therethrough. Device **320** is collapsed after use for removal. To collapse the device for withdrawal, frame wire **332** is moved proximally, as illustrated by arrow **346** in FIG. **24**, to collapse or close external loop **342** to the low-profile collapsed dimension illustrated in FIG. **23**.

In the embodiment illustrated in FIGS. **23–24**, a pressure-sensing device **350** may be inserted through lumen **326** of guidewire **322**. The pressure-sensing device **350** is formed of an elongated member **352** having a distal tip **354** which is curve-shaped to align a pressure sensor facing the direction of blood flow or fluid flow through vessel **60**. Proximal circuitry is coupled to the pressure sensor at distal tip **354** to provide a pressure reading to an operator. Of course, device **350** may simply be a hollow tube with the pressure sensing mechanism located entirely at a proximal end of device **350**. The pressure reading indicates whether the blood vessel or vascular vessel **60** is occluded distal of protection device **320**, to ensure proper blood flow through protection device **320**. Thus, if emboli, particles, or debris clogs filter **328** of distal protection device **320**, the pressure will drop, thus indicating restricted blood flow for real-time monitoring of blood flow through the distal protection device **320**. Use of a pressure sensor provides advantages over use of dye-injection techniques to provide continuous real-time quantitative measurement of blood flow for monitoring operation.

Although the protection devices described are illustrated for use as temporary filters, it should be understood that the devices of the present invention are not so limited and may be used for permanent filters which are retained in a patient to filter debris and clotting material. Although the present invention has been described with reference to preferred embodiments, workers skilled in the art will recognize that changes may be made in form and detail without departing from the spirit and scope of the invention.

What is claimed is:

1. A device adapted for deployment in a body vessel, comprising:

a filter having a plurality of openings for fluid flow therethrough; and

a proximally-tapered collapsible frame coupled to the filter and operably coupled to a guidewire, said frame including an expandable mouth coupled to the filter and adapted to operate between an expanded profile and a collapsed profile, and general longitudinal ribs having opposed first and second ends, said first ends being coupled to the guidewire, and said second ends being coupled to the mouth, said ribs being sloped outwardly in an expanded position to form the proximally tapered collapsible frame; the frame being biased to expand from the collapsed profile to the expanded profile.

2. The device of claim **1** wherein the mouth is normally biased in the expanded profile.

3. The device of claim **2** wherein the mouth is formed of a resilient wire material.

4. The device of claim **1** wherein the mouth and ribs are integrally formed from a mesh sheet material.

5. The device of claim **1** wherein the filter has a distal end fixedly coupled to the guidewire.

6. The device of claim **1** wherein the filter is generally cone-shaped.

7. The device of claim **1** wherein mouth is formed of a pleated ring.

8. The device of claim **7** wherein the pleated ring includes at least four folds.

9. The device of claim **1** wherein ribs are fixedly secured to the guidewire.

10. The device of claim **1** and further comprising a collar slidably disposed over the guidewire and wherein the ribs are coupled to the collar, the guidewire extending through the mouth and along a length of the filter.

11. The device of claim **1** wherein the frame includes at least four ribs.

12. The device of claim **1** wherein the mouth and ribs are integrally formed.

13. In combination:

a device adapted for deployment in a body vessel including:

a filter having a plurality of openings for fluid flow therethrough, said filter being adapted to be coupled to a wire for operation;

a proximally-tapered collapsible frame coupled to the filter and operably coupled to a core wire, said frame including an expandable mouth adapted to operate between an expanded profile and a collapsed profile, and sloped longitudinal ribs having opposed first and second ends, said first ends being coupled to the wire and said second ends being coupled to the mouth, said ribs being sloped outwardly in the expanded profile to form the proximally-tapered collapsible frame, the frame being biased to expand from the collapsed profile to the expanded profile; and

a sheath formed of a tubular member sized for placement over the ribs to collapse the mouth and filter to the collapsed profile.

14. A method for deploying a device in a vessel for collecting debris, comprising the steps of:

providing a device coupled to a guidewire and movable relative thereto, having a filter and a frame for supporting the filter in a collapsed profile and an expanded deployed profile, said frame being normally biased in the expanded deployed profile;

providing an elongated sheath having proximal and distal ends and an inner lumen extending therethrough;

positioning the device in the lumen of the sheath to maintain the device in a collapsed profile;

inserting the sheath and device into a body lumen and advancing the distal end of the sheath to locate the device at a deployment site;

proximally moving the sheath to withdraw the sheath while maintaining the position of the guidewire to remove the sheath from the device to expand the frame and filter; and

wherein the guidewire is inserted prior to insertion of the device, and the device is advanced over the guidewire for placement at the deployment site and is locked to the guidewire prior to withdrawal of the sheath.

15. The method of claim **14** wherein the guidewire is concurrently inserted with the device and sheath.

* * * * *

US005161534A

United States Patent [19]

Berthiaume

[11] Patent Number: 5,161,534

[45] Date of Patent: Nov. 10, 1992

[54] **TOOL FOR MANIPULATING A MEDICAL GUIDEWIRE**

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[21] Appl. No.: **755,094**

[22] Filed: **Sep. 5, 1991**

[51] **Int. Cl.**[5] **A61B 6/00**

[52] **U.S. Cl.** **128/657**; 604/159; 226/127

[58] **Field of Search** ..... 128/657, 772; 606/180, 606/225; 604/95, 117, 159, 280; 24/136 L, 136 R; 226/127, 196

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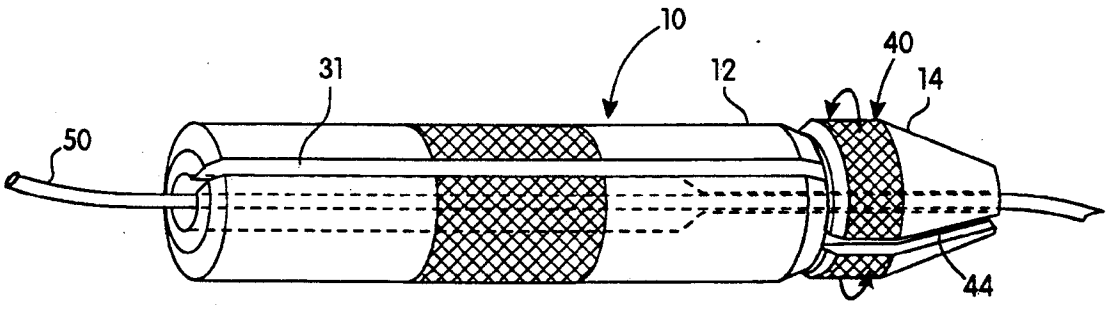
Primary Examiner—Max Hindenburg
Attorney, Agent, or Firm—Wolf, Greenfield & Sacks

[57] **ABSTRACT**

A laterally attachable and detachable tool for manipulating a guidewire includes a cylindrical body that terminates in a collet. A nut is threaded to the collet and can be tightened to draw the collet arms inwardly. The body and the nut each include a lateral slot of a width to receive the guidewire. The slot in the nut is registrable with the slot in the body to form a continuous slot, receptive to the guidewire, along the length of the tool.

11 Claims, 1 Drawing Sheet



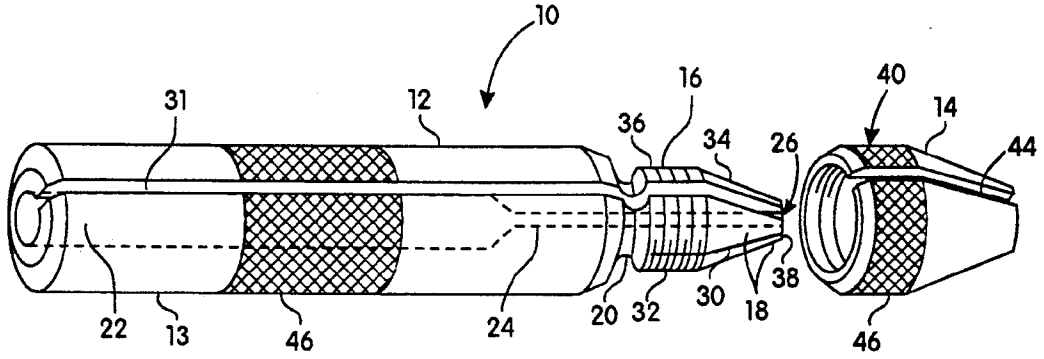


Fig. 1

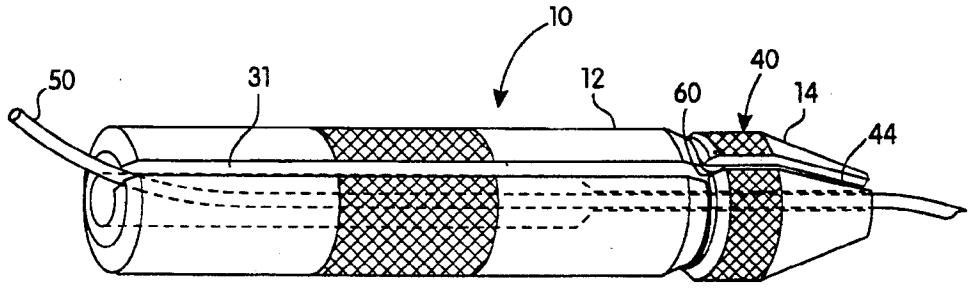


Fig. 2

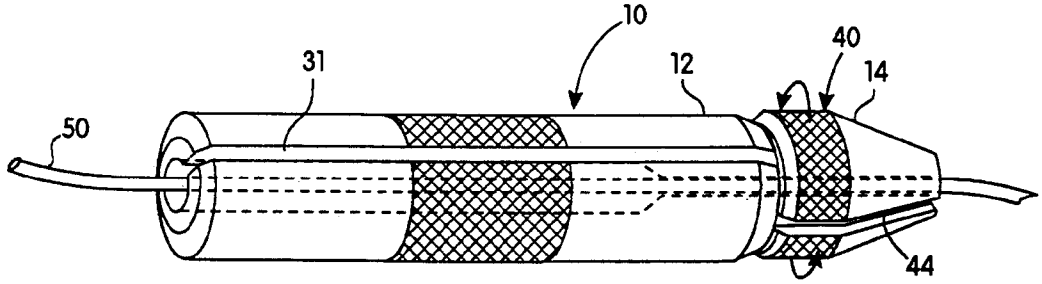


Fig. 3

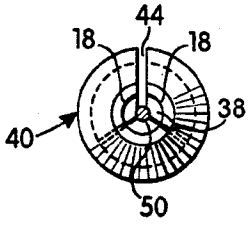


Fig. 4

TOOL FOR MANIPULATING A MEDICAL GUIDEWIRE

FIELD OF INVENTION

The present invention relates to a tool for manipulating a medical guidewire and, more particularly, to a tool that is longitudinally and laterally attachable to and detachable from the guidewire.

BACKGROUND OF THE INVENTION

Guidewires are well known for placing and guiding catheters and other devices in the vascular network of the human body. In a common type of procedure a guidewire is inserted percutaneously into an easily accessed blood vessel. The guidewire then is manipulated to steer the guidewire through the vascular network until the distal end (the end inside the patient) reaches a desired location. The catheter may be inserted preassembled with the guidewire or the catheter may be inserted and advanced over a previously placed guidewire.

The steerability of the guidewire is important especially when a tortuous path must be navigated to reach the target site as is commonly encountered when placing a catheter in the coronary arteries. Steering is executed from the proximal end of the guidewire (outside of the patient) by rotating, pushing and pulling on the guidewire to cause corresponding movement at the distal tip of the wire. The distal tip typically has a slight bend so that when rotated it can be directed toward a selected one of several vascular branches. The distal tip of the guidewire typically is radiopaque so that its movement can be observed under x-ray fluoroscopy. Steering of the guidewire directly by hand has proven difficult because of the small diameter (0.010" to 0.038") and high flexibility of the guidewire. In addition some guidewires have a lubricious surface coating and tend to slip out of the user's grasp.

Steering tools have been developed to alleviate the foregoing problems. Typical is a device sold under the trade designation Steering Handle by U.S.C.I., a division of C.R. Bard, Inc. The device includes a hollow cylindrical body having a central bore and tapered collet for firm attachment to the guidewire. The device is substantially greater in diameter than the guidewire and is more easily gripped and rotated. The device is threaded onto the guidewire over an end of the guidewire and is slid along the guidewire to a location convenient for the physicians. The collet then is tightened securely around the guidewire.

To avoid having to slide the steering tool along the guidewire, laterally mountable steering devices have been developed. U.S. Pat. No. 4,726,369 discloses a steering tool including a resilient cylindrical body with an axial bore and a surrounding sleeve. Radial, longitudinally extending slots on the sleeve and the cylindrical body are aligned to form a continuous slot through which the guidewire can be laterally inserted and removed. To hold the guidewire in place, the sleeve is squeezed causing the resilient cylindrical body walls to compress against the guidewire. The device disclosed in U.S. Pat. No. 4,726,329 is not well suited for use when the traditional longitudinal mounting procedure is required or preferred.

SUMMARY OF THE INVENTION

The present invention is a tool for manipulating a guidewire. The tool either may be laterally or longitudinally mounted to the guidewire. The tool comprises an elongated main body that includes a cylindrical portion and a collet portion. A bore extends axially through the main body and opens laterally through the surface thereof. The collet portion includes four circumferentially spaced fingers which respectively are separated by slots extending radially through the surface of the collet. The surface of the collet portion is threaded for engagement with a nut. The nut includes a laterally extending slot that is alignable with the lateral opening in the elongated main body. The lateral opening in the elongated main body and the laterally extending slot in the nut are sized to receive the guidewire. When aligned, the laterally extending slot in the nut and the lateral opening in the elongated main body form a continuous elongated lateral slot that permits side-mounting of the tool onto the guidewire. After the tool is mounted about the guidewire, the nut is tightened until the guidewire is securely engaged between the inwardly compressed collet arms.

It is among the general objects of the invention to provide a tool that is mountable to a guidewire that already is positioned within the patient's body.

It is a further object of the invention to provide a tool that is mountable either laterally or longitudinally to a guidewire.

DESCRIPTION OF THE DRAWINGS

The foregoing and other objects and advantages of the invention will be appreciated more fully from the following drawings in which:

FIG. 1 is a perspective view, partly in phantom, of the guidewire manipulating tool in accordance with the invention;

FIG. 2 is a perspective view, partly in phantom, of the guidewire manipulating tool being laterally mounted to the guidewire;

FIG. 3 is a perspective view, partly in phantom, of the guidewire manipulating tool in accordance with the invention with the guidewire fixedly positioned within the tool; and

FIG. 4 is an end view of the guidewire manipulating tool in accordance with the invention showing the guidewire fixedly positioned between the collet arms.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

The guidewire manipulating tool **10** shown in FIG. **1** includes a body **12** and a nut **14** threaded onto an end of the body. The body **12** may be considered as having a proximal end (to the left in FIG. **1**) and a distal end (to the right in FIG. **1**). The body **12** includes a cylindrical portion **13** at its proximal end and an integral collet portion **16** at its distal end. The collet **16** is tapered distally and includes four circumferentially spaced arms **18** separated by radial, longitudinally extending slots **30**. A reduced diameter **20** neck extends between the collet **16** and the cylindrical portion **13**.

The body **12** includes a longitudinally extending bore **22** that narrows at tapered portion **24** from a wider diameter at the proximal end to a narrower diameter diameter **26** at its distal portion. The bore **22** passes through the collet **16** and is open at the distal end defining an exit opening **26**. The bore **22** also is exposed

laterally through a radial, longitudinally extending slot **31** formed in the body **12**. The slot **31** is sized to permit passage of a guidewire. In the preferred embodiment, the slot has a width of at least 0.020 inches in order to accommodate commercially available coronary guidewires that range typically between 0.010 and 0.018 inches. Preferably, one of the slots **30** in the collet **16** is a continuation of the lateral slot **31** and may be wider than the other slots **30** in the collet.

The collet **16** includes a substantially constant diameter threaded portion **32** and a distally tapering, generally conical portion **34** The front edges **38** of the collet arms **18** are bevelled to provide collectively a concave surface for facilitating mounting of the tool **10** to the guidewire in the traditional longitudinal fashion. The nut **14** includes an internal conical surface that is drawn against and closes the collet arms **18** when the nut **14** is tightened about the collet **16**. The nut **14** includes a lateral, longitudinally extending slot **44** that is alignable with the slot **31** in the tool **10**. The slot **44** also is sized to receive a guidewire and, preferably, has a width of at least 0.020 inches. The surface of the main body **12** and the nut **14** may be knurled **46** to enhance the users grip on the device.

The main body **12** and the nut **40** preferably are formed of brass or other metal such as aluminum, stainless steel or alloys of brass, aluminum or stainless steel. Hard plastics such as polyvinylchloride, acrylics, polycarbonate or polystyrene also are contemplated. In one alternative embodiment, the device includes a plastic body and a metal collet bonded with an adhesive to the distal end thereof. The collet or the outer surface of the distal end may be threaded for engagement with the metal nut. In a preferred embodiment, the tool is 2 inches long and has an outside diameter of between 0.250 inches and 0.3125 inches. The diameter of the longitudinally extending bore ranges from 0.020 inches to 0.030 inches.

The lateral mounting of the tool **10** on a guidewire **50** is shown in FIGS. **2-3**. The nut **14** loosely is threaded on the collet **16** with the slot **44** in the nut **14** aligned with the slot **31** in the body **12**, thus defining a continuously open slot receptive to the guidewire **50**. The tool **10** then is laterally mounted onto the guidewire **50** and the nut **14** is tightened to cause the collet arms **18** to grip the guidewire **50** as shown in FIG. **4**. Once the nut **40** is sufficiently tightened, the guidewire may be steered or otherwise manipulated by movement of the tool **10** to which it is securely attached. The tool **10** is removed easily from the guidewire by loosening the nut **40** to release the grip of the collet arms **18**. The slot **44** in the nut **14** then is aligned with the slot **31** in the body **12** to permit lateral detachment of the tool from the guidewire **50**.

The tool **10** also may be mounted on the guidewire **50** in the traditional longitudinal manner by threading the device onto an end of the guidewire. With the nut **14** loosely threaded onto the collet **16**, the tool **10** may be threaded onto the proximal or the distal end of the guidewire **50** and slid along the guidewire to a location convenient for the physician. After the tool has been advanced to the desired location on the guidewire **50**, the nut **14** is tightened to lock the tool to the guidewire.

It should be understood that the foregoing description of the invention is intended merely to be illustrative thereof and that other equivalents, embodiments and modifications of the invention may be apparent to those skilled in the art.

What is claimed is:

1. A tool for manipulating a guidewire, comprising:

an elongated body having a bore extending therethrough and a longitudinal slot extending radially from said bore through the surface of said elongated body, said slot and said bore being adapted to receive the guidewire;

one end of said elongated body including a collet portion, said collet portion having a plurality of radial, longitudinally extending slots extending from said elongated bore through the surface of said collet portion, a portion of said surface of said collet portion being threaded; and

a nut threadably mounted to said collet portion and having a bore extending therethrough, said nut having a radial, longitudinally extending slot extending radially from said nut bore through the surface of said nut, said radial, longitudinally extending slot in said nut being registerable with said radial, longitudinally extending slot in said elongated body to form a continuous elongated slot along the length of said tool, said continuous elongated slot being adapted to receive the guidewire.

2. The tool recited in claim **1** wherein each of said plurality of radial, longitudinally extending slots in said collet portion is narrower than said radial, longitudinally extending slot in said body.

3. The tool recited in claim **1** wherein one of said plurality of radial, longitudinally extending slots in said collet portion includes said radial, longitudinally extending slot in said body.

4. The tool recited in claim **3** wherein said one of said plurality of radial, longitudinally extending slots in said collet portion is wider than the other of said plurality of radial, longitudinally extending slots in said collet portion.

5. The tool recited in claim **3** wherein said one of said plurality of radial, longitudinally extending slots in said collet portion is a continuation of said radial, longitudinally extending slot in said body.

6. The tool recited in claim **1** wherein said radial, longitudinally extending slot in said body has a width of at least 0.020 inches.

7. The tool recited in claim **6** wherein one of said plurality of radial, longitudinally extending slots in said collet portion has a width of at least 0.020 inches.

8. The tool recited in claim **7** wherein said radial, longitudinally extending slot in said nut has a width of at least 0.020 inches.

9. The tool recited in claim **1** wherein said radial, longitudinally extending slot in said body and said radial, longitudinally extending slot in said nut have the same width.

10. The tool recited in claim **1** wherein said continuous elongated slot has a uniform width.

11. A tool for manipulating a guidewire comprising:

an elongated body having a bore extending axially therethrough, said elongated body having an opening laterally extending from said elongated bore through the surface of said elongated body, said laterally extending opening in said body being adapted to receive the guidewire;

said elongated body including a collet portion having a plurality of spaced slots radially extending from said elongated bore through the surface of said collet portion, one of said plurality of spaced radially extending slots including said laterally extending opening extending through said collet portion

and having a width larger than the width of the other of said plurality of spaced radially extending slots, a portion of said surface of said collet portion being threaded; and

a nut threadably mounted to said collet portion and having a bore extending axially therethrough, said nut having a slot laterally extending from said bore through the surface of said nut, said laterally extending slot in said nut being alignable with said laterally extending opening in said elongated body to form a continuous elongated slot along the length of said tool, said continuous elongated slot being adapted to receive the guidewire.

* * * * *

Aug. 5, 1969 W. H. RING 3,459,184

INTRAVENOUS CATHETER PLACEMENT UNIT

Filed Nov. 4, 1966 2 Sheets-Sheet 1

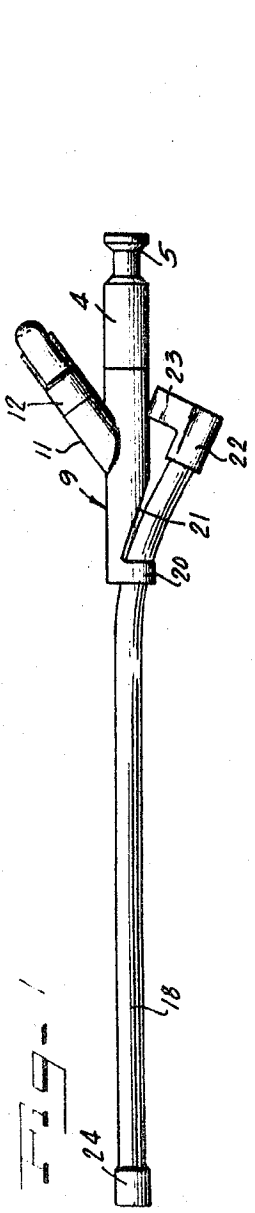


Fig. 1

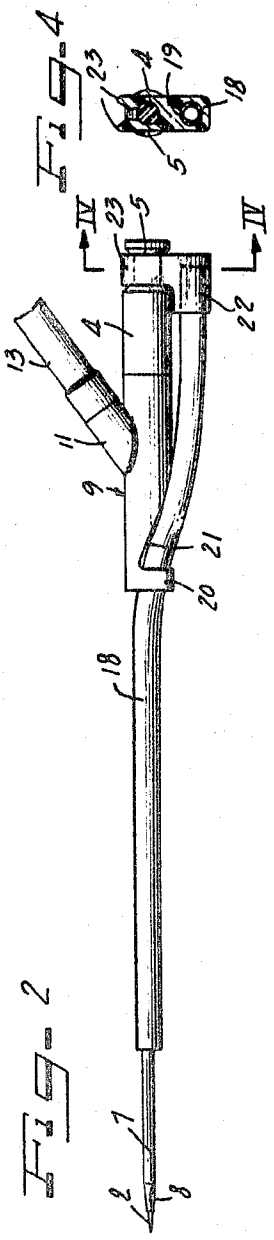


Fig. 2

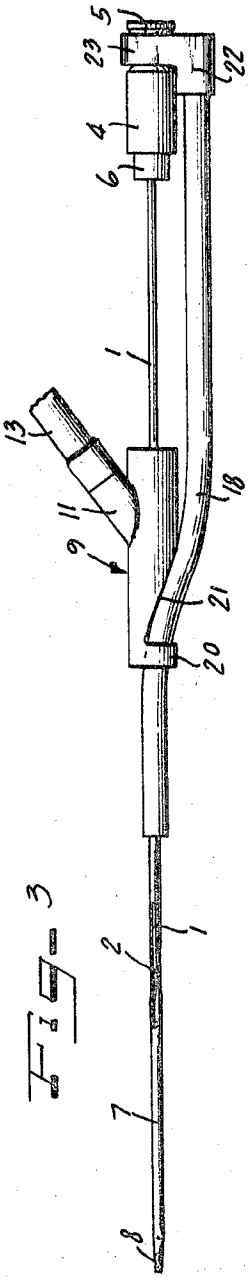


Fig. 3

Fig. 4

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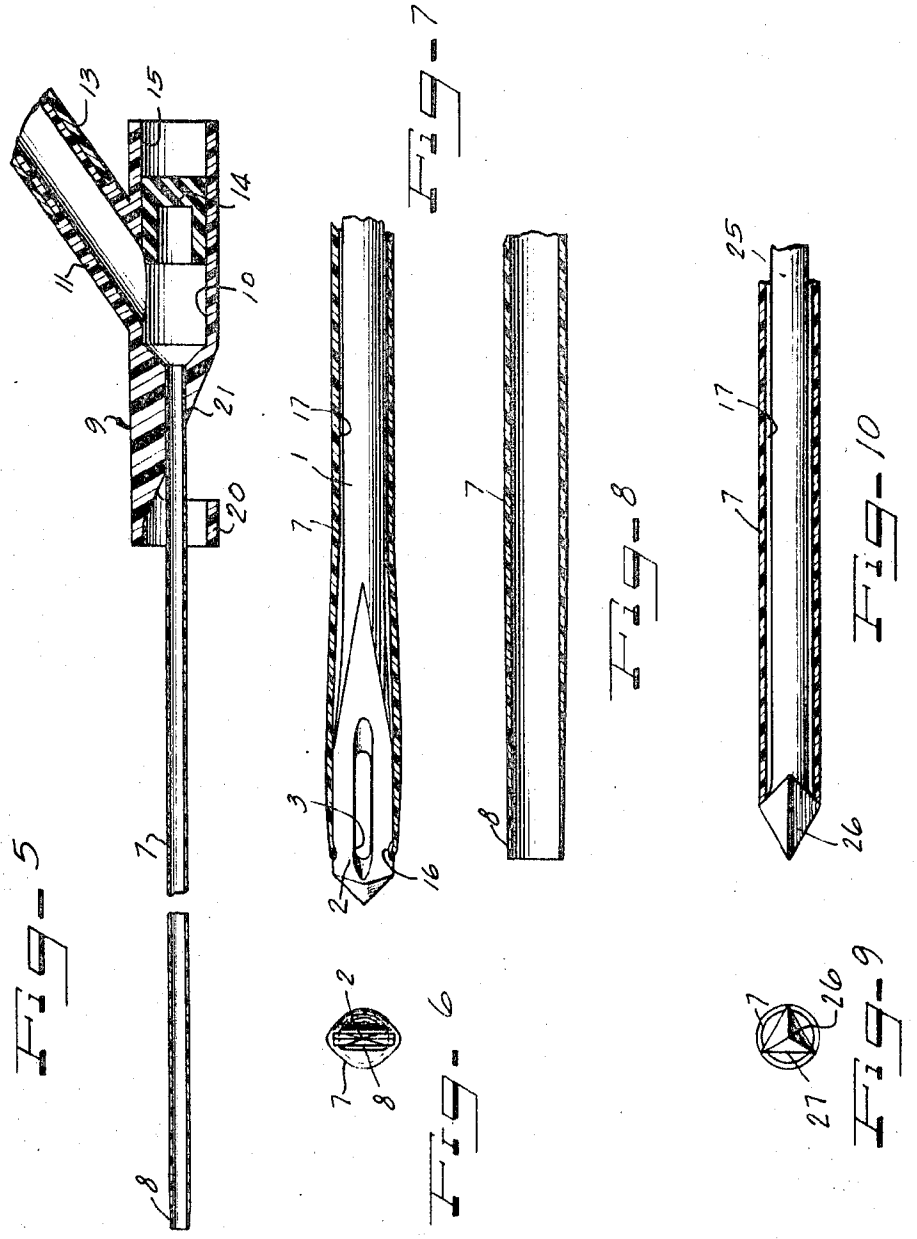
Aug. 5, 1969 W. H. RING 3,459,184

INTRAVENOUS CATHETER PLACEMENT UNIT

Filed Nov. 4, 1966 2 Sheets-Sheet 2



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United States Patent Office 3,459,184 Patented Aug. 5, 1969

3,459,184

INTRAVENOUS CATHETER PLACEMENT UNIT

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Filed Nov. 4, 1966, Ser. No. 592,031
Int. Cl. A61m 5/00, 25/00
U.S. Cl. 128—214.4 5 Claims

ABSTRACT OF THE DISCLOSURE

A unit for placing a catheter in a body lumen with the aid of a needle, both catheter and needle remaining in a sterile sheath until properly and completely positioned with the body lumen, whereby no sterile field of operation is necessary, and with which unit both the sheath and needle are completely removable after placement of the catheter leaving only a fitting which connects the catheter to a source of infusion remaining for attachment to the patient's body.

Many times it is desirable to place a catheter in a body lumen with the aid of a solid needle around which the catheter is disposed to obtain the advantages of easier cutaneous perforation, avoid leakage of blood or infusion liquid, and to have the catheter completely filling the cutaneous puncture, which advantages are not often obtainable by using a cannulated needle telescopically associated with the catheter. In the past, however, catheter placement units embodying a catheter telescopically associated with a solid needle were objectionably limited as to the length of catheter that could be utilized, because the catheter was advanced along with the needle into the body lumen to its desired extent, and thereafter the needle withdrawn from the already advanced catheter. A needle over 2½ inches in length is difficult to hold and direct in performing a venipuncture, without danger of contamination of the needle, and if a longer needle is gripped near the proximal end thereof, there is danger of injury to the patient by virtue of the needle bending during venipuncture. Also, it is not desirable in most cases to insert any longer needle into a vein or other body lumen because of the danger of puncturing the lumen wall. Further, with devices of this character as heretofore made, the catheter was not advanced into the body lumen relatively to the needle, and the catheter could not be advanced into the body lumen while infusion takes place.

With the foregoing in mind, it is an important object of the instant invention to provide a catheter placement unit utilizing a solid needle telescopically associated with a catheter so arranged that the catheter may be advanced into a body lumen relatively to the needle while infusion takes place to substantially any desirable extent, even to the vicinity of the heart for the determination of central venus pressure, by virtue of the fact that the unit may be made in any desirable length and facilely used without endangering the patient.

Another important object of this invention is the provision of a catheter placement unit embodying a solid needle and catheter telescopically associated, which unit may be made with a catheter of any desirable length, and both the catheter and needle being maintained in a sterile condition until the catheter is completely advanced into a body lumen.

It is also an object of this invention to provide a catheter placement unit embodying a solid needle and the arrangement between the catheter and needle being such that a flow of blood will be visible in the catheter when a venipuncture has been accomplished so that the operator will know that the tip of the catheter is within the body lumen of a patient.

A further object of this invention resides in the provision of a catheter placement unit embodying a solid needle and a catheter of substantially any desired length, the catheter and needle being enclosed within a sterile sheath, and means are provided for locking the sheath and needle together so that after advancement of the catheter, both the needle and sheath are easily withdrawn, leaving only the catheter extending into the body lumen of a patient and the connection between that catheter and the infusion system.

While some of the more salient features, characteristics and advantages of the instant invention have been above pointed out, others will become apparent from the following disclosures, taken in conjunction with the accompanying drawings, in which:

FIGURE 1 is a side elevational view of a catheter placement unit embodying principles of the instant invention, as the same appears when first removed from a wrapper for use;

FIGURE 2 is a fragmentary view of the placement unit adjusted for the making of a venipuncture;

FIGURE 3 is a fragmentary side elevational view, with parts broken away, illustrating the advancement of the catheter into a body lumen;

FIGURE 4 is a vertical sectional view taken substantially as indicated by the line IV—IV of FIGURE 2, looking in the direction of the arrows;

FIGURE 5 is a central vertical sectional view of only the catheter and the advancer-fitting for connecting the same to the infusion system;

FIGURE 6 is a greatly enlarged end elevation of the needle head and catheter;

FIGURE 7 is a greatly enlarged fragmentary view, with the catheter in section, showing the relationship of the catheter with the needle head;

FIGURE 8 is a fragmentary vertical sectional view of the catheter alone;

FIGURE 9 is an end elevational view showing the relationship between the catheter and a needle head of different form; and

FIGURE 10 is a fragmentary view showing the association of the catheter with the needle, the catheter being shown in section.

As shown in the drawings:

The illustrated embodiment of the instant invention seen in FIGURES 1 to 8 inclusive, includes a solid needle **1** having a flattened spearhead **2** on the distal end thereof to enable easy piercing, as best seen in FIGURES 6 and 7. An elongated, axially extending slot **3** is provided in the spearhead **2** to enable blood to enter the catheter at the time of venipuncture. At the proximal end thereof the needle is provided with a hub **4** which may readily be molded with a suitable plastic, such as nylon, polyethylene, or any other suitable material. The needle end is firmly embedded and secured within the hub **4**. The outer end of the hub is provided with an annular groove **5** therein reducing the diameter of the hub at that point for later engagement by another portion of the placement unit, as will later appear. The inner end of the hub is also reduced in diameter as indicated at **6** for telescopic engagement with the advancer-fitting on the catheter.

Telescopically associated with the needle **1** is a catheter **7** formed from any suitable transparent plastic material. As seen best in FIGURE 8, the internal diameter of the catheter is preferably constant throughout the length of the catheter, but the distal end of the catheter is tapered from the outside so that the wall thins to a narrow edge defining the distal end of the catheter, as indicated at **8**.

As seen best in FIGURE 5, the proximal end of the catheter is fused or otherwise firmly secured within the bore of a tubular fitting, generally indicated by numeral

9, which fitting functions both as a means for advancing the catheter and also as a means of connecting the catheter to an infusion system. The outer portion of the fitting 9 is interiorly enlarged to provide a passage or chamber 10 in communication with the catheter. The fitting also includes a tubular nipple 11 extending upwardly at an angle to the body of the fitting. The inner end of the nipple 11 communicates directly with the aforesaid chamber 10, and the outer end initially is closed by a removable cap 12 until the placement unit is put to use when the cap is removed and the nipple is connected to an infusion tube 13 leading from a source of infusion liquid. The cap 12 maintains the sterility of the interior of the fitting until it is desired to place the catheter. Within the chamber 10 outward of the communication with the nipple 11 a plug 14 of self-sealing material is firmly secured, this plug being satisfactorily made of soft rubber. As seen in FIGURE 5, the plug is so disposed as to leave a recess 15 outward thereof for the reception of the smaller inner end 6 on the needle hub.

When the catheter and fitting arrangement is assembled with the needle, the needle extends centrally through the plug 14, the chamber 10, and through the catheter with the spearhead of the needle projecting just beyond the distal end of the catheter as seen in FIGURES 2 and 7, in the illustrated embodiment of the invention. Initially, before usage, the end portion 6 of the needle hub is seated within the recess 15 in the catheter fitting.

With reference to FIGURE 7, it will be seen that the reduced distal end 8 of the catheter terminates adjacent the point of the needle but beyond the widest part of the needle spearhead 2, flexibility of the catheter permitting it to be distorted to correspond with the shape of the spearhead, as seen best in FIGURE 6. Upon insertion into a body lumen with the needle withdrawn, the inherent resiliency of the catheter will restore the end portion 8 to its original circular shape. If so desired, the needle may be provided with opposed notches 16, as seen in FIGURE 7, to receive the distal end of the catheter to better maintain the catheter and needle in their relative positions until venipuncture has been accomplished.

It will be noted that the slot 3 in the needle spearhead extends toward the point of the needle beyond the end of the catheter so that when venipuncture is made blood may enter the catheter by way of the slot 3. Also, as seen in FIGURE 7 the catheter has an inside diameter slightly larger than the diameter of the needle, thus providing a space 17 to receive blood and make known to the operator that the catheter has properly entered a body lumen.

The catheter and needle are maintained in a sterile condition by a sheath 18 having a slit, indicated at 19 in FIGURE 4, extending lengthwise of the sheath along the top side thereof. The sheath is made from a suitable plastic material, such as polyethylene, and no sealing means are required at the slit, since the resiliency of the sheath tends to maintain the slit closed. The sheath is also transparent, and while sufficiently flexible for the intended purposes, it is, of course, much more rigid than the catheter. The sheath itself is of the same construction as the sheath illustrated and described in W. H. Ring et al. U.S. Patent No. 3,262,448 dated July 26, 1966. The sheath extends through a loop 20 which may be integrally formed on the end of the catheter fitting 9, and behind that loop the fitting is provided with a downwardly and outwardly inclined surface 21 to cause the sheath to bend away from the catheter and needle during manipulation of the placement unit, as seen in FIGURES 2 and 3, the slit 19 of the sheath opening sufficiently to permit the sheath to be readily drawn off the catheter and needle. At the proximal end thereof, the sheath terminates inside an end plug 22 which is provided with a pair of upstanding confronting tooth-like projections 23 for snap-on and gripping engagement with the needle hub inside the groove 5, as seen in FIGURES 2 and 4. With reference to FIGURE 1, it will be seen that at the outset the distal end of the sheath is covered by a temporary cap 24 for the maintenance of sterility. After the various parts of the placement unit have been sterilized and assembled for packaging, the unit appears as viewed in FIGURE 1 with both the caps 12 and 24 in place and the catheter and needle fully protected by and enclosed within the fitting 9 and the catheter sheath. The catheter sheath is extended so as to extend beyond the needle point, and is uncoupled from the needle hub, the locking teeth 23 being disposed against the underside of the fitting 9 with the catheter sheath in a bent condition.

When it is desired to utilize the placement unit, it is removed from the wrapper, the cap 12 on the fitting nipple 11 removed and the nipple connected to an infusion tube 13. Then the cap 24 is removed and by grasping the plug 22 and holding the fitting, the sheath is pulled outwardly to the position seen in FIGURE 2 and locked to the needle hub as explained above, thus leaving exposed aproximately 1½ inches of the needle and surrounding catheter. If desired, at that time the catheter may be flushed with infusion liquid to clear it of air and any sterilization sediment that might have been in it. Venipuncture may now be made by the operator grasping the needle by squeezing the sheath in the distal portion thereof, so that regardless of the actual length of the needle the operator is utilizing a short length thereof so there is no danger of the needle bending during venipuncture. As soon as venipuncture has been made and revealed to the operator by blood flowing outwardly through the catheter, the needle hub is held and the fitting 9 moved along the needle as indicated in FIGURE 3, to advance the catheter beyond the end of the needle and relatively to the needle. Infusion may be turned on as soon as venipuncture is accomplished, and the catheter is advanced while infusion is taking place, the catheter being internally larger than the needle readily permitting this infusion and the catheter easily flexing during its advancement over the wider part of the needle spearhead. When the catheter is fully advanced, the fitting 9 is held by the operator and by gently pulling upon the needle hub both the needle and the sheath are withdrawn completely away, the self-sealing plug 14 preventing any leakage from the outer end of the fitting 9 during the operation and thereafter. Only the catheter and fitting are left attached to the patient, the fitting being connected to the patient's arm by a suitable piece of adhesive tape or in an equivalent manner. The entire operation may be accomplished without the need of a sterile field and with complete asepsis since the operator's hands never touch anything that enters the patient's body, it being only necessary to appropriately prepare the skin at the venipuncture site. The catheter may be of any length that the physician or surgeon requires. Since the catheter initially overlies and extends beyond the widest portion of the needle head and is supported thereby, there is no danger of the catheter moving relatively to the needle during venipuncture. When the catheter is advanced, with the needle functioning as a stylus, the catheter offers negligible resistance in passing over the widest part of the needle head.

In FIGURES 9 and 10 I have illustrated the placement unit embodying a needle of somewhat different configuration than the needle above described, the exact type of needle point being left to the choice of the physician or surgeon. In this instance a needle 25 is utilized of lesser diameter than the inside diameter of the catheter 7, leaving the space 17 between the catheter and the needle. The needle has a triangular head 26 facetted to a point, and the catheter terminates just to the rear of the points of the triangle so that it projects laterally from the needle from the sides of the triangular head as indicated at 27 in FIGURE 9. In this instance, the needle head protects the catheter during venipuncture so there is no relative movement between them, and when it is desired to advance the catheter very little pressure is required to cause the

catherer to assume the shape of the needle head in general and pass over the points of the triangular head. The structure of FIGURES 9 and 10 is utilized in the same manner above described.

Various forms of needle heads may be used, the physician or surgeon having a wide choice in this regard.

It will be understood that modifications and variations may be effected without departing from the scope of the novel concepts of the present invention.

I claim as my invention:

1. In a catherer placement unit,
an elongated needle,
a hub on the proximal end of said needle,
a catherer telescopically surrounding said needle,
a sheath longitudinally slit and more rigid than said catherer enclosing said catheter and needle,
an advancer-fitting connected to the proximal end of said catheter to connect the catheter to an infusion system and advance the catheter relatively to said needle and through which said needle extends,
said sheath being withdrawable to expose a sufficient portion of the catheter and needle for entering a body lumen, and
interlocking means on said needle hub and the proximal end of said sheath operable upon partial withdrawal of said sheath for joint removal with said needle.

2. The catheter placement unit of claim 1, including means on said advancer-fitting slidable along said sheath to maintain said advancer-fitting in alignment with said needle.

3. The catheter placement unit of claim 1, including a loop on the distal end of said advancer-fitting embracing said sheath to maintain proper alignment of said advancer-fitting.

4. The catheter placement unit of claim 3, including a downwardly and outwardly inclined surface on said advancer-fitting proximally of said loop to cause said sheath to bend away from said catheter and needle during advancement of the catheter.

5. The catheter placement unit of claim 1, wherein said interlocking means include said needle hub having a groove therein, and a plug on the end of said sheath having spaced projections for snap-on engagement in said groove.

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DALTON L. TRULUCK, Primary Examiner

U.S. Cl. X.R.

128—221